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EXHIBIT 1

US007585311B2

(12) **United States Patent**
Green et al.

(10) **Patent No.: US 7,585,311 B2**
(45) **Date of Patent: Sep. 8, 2009**

(54) **SYSTEM AND METHOD FOR ATTACHING SOFT TISSUE TO BONE**

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(73) Assignee: **KFx Medical Corporation**, Carlsbad, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 749 days.

(21) Appl. No.: **11/143,007**

(22) Filed: **Jun. 1, 2005**

(65) **Prior Publication Data**

US 2006/0004364 A1 Jan. 5, 2006

Related U.S. Application Data

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(51) **Int. Cl.**
A61B 17/04 (2006.01)

(52) **U.S. Cl.** **606/232**

(58) **Field of Classification Search** 606/232, 606/72, 75, 78, 219, 224
See application file for complete search history.

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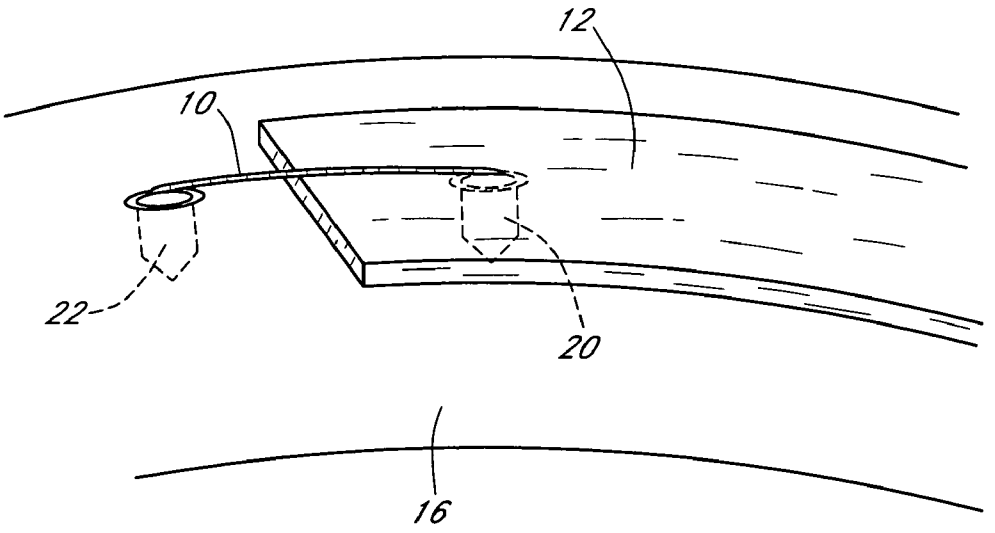
Primary Examiner—(Jackie) Tan-Uyen T. Ho
Assistant Examiner—Gregory A Anderson
(74) *Attorney, Agent, or Firm*—Knobbe, Martens, Olson & Bear LLP

(57) **ABSTRACT**

Disclosed herein are methods and devices for securing soft tissue to a rigid material such as bone. A bone anchor is described that comprises a base and a top such that suture material may be compressed between surfaces on the base and top to secure the suture to the anchor. Also described is an inserter that can be used to insert the bone anchor into bone and move the anchor top relative to the anchor base to clamp suture material there between. Also described is a soft-tissue and bone piercing anchor and associated inserter. Methods are described that allow use of the bone anchors to provide multiple lengths of suture material to compress a large area of soft tissue against bone.

30 Claims, 24 Drawing Sheets



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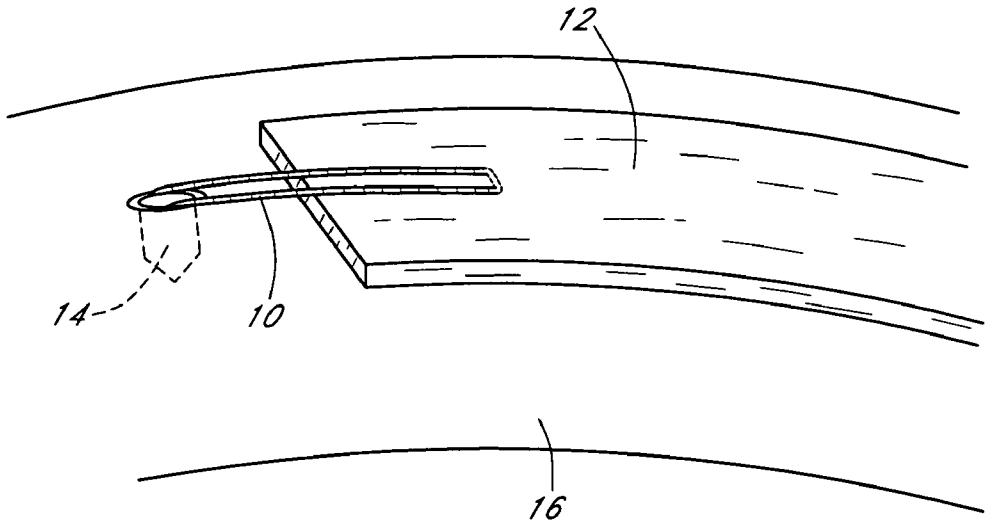

FIG. 1

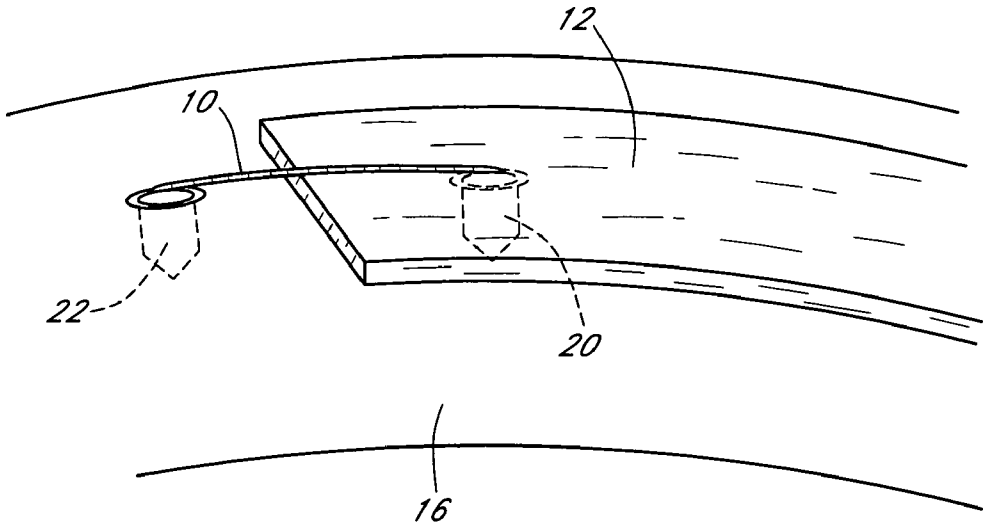

FIG. 2

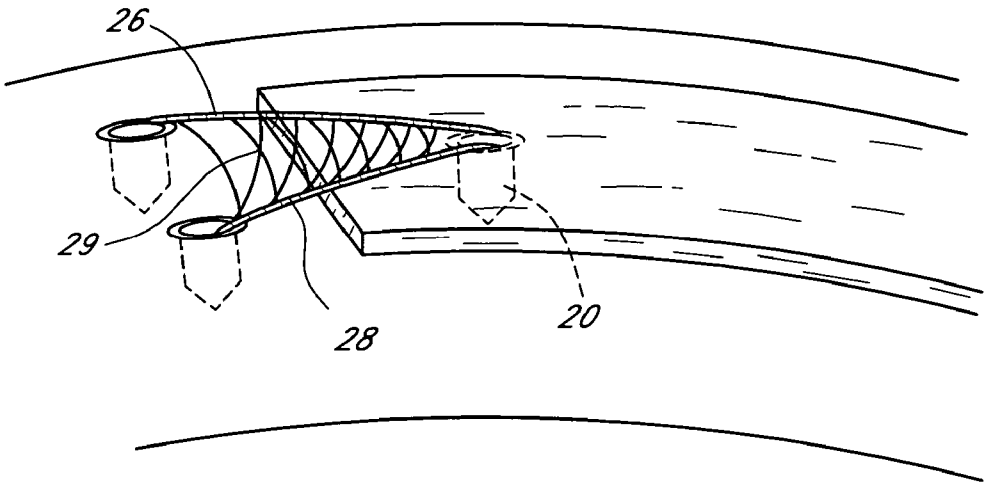

FIG. 3A

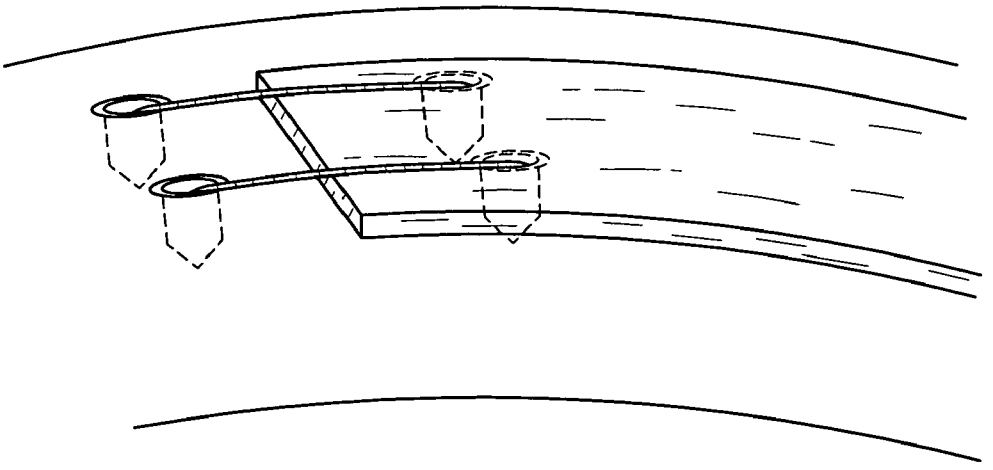

FIG. 3B

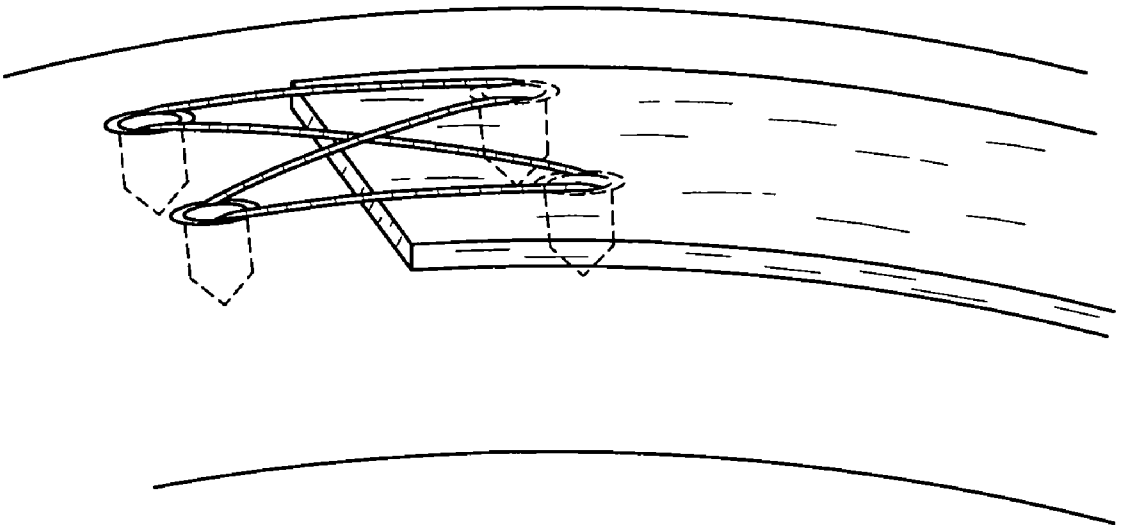

FIG. 3C

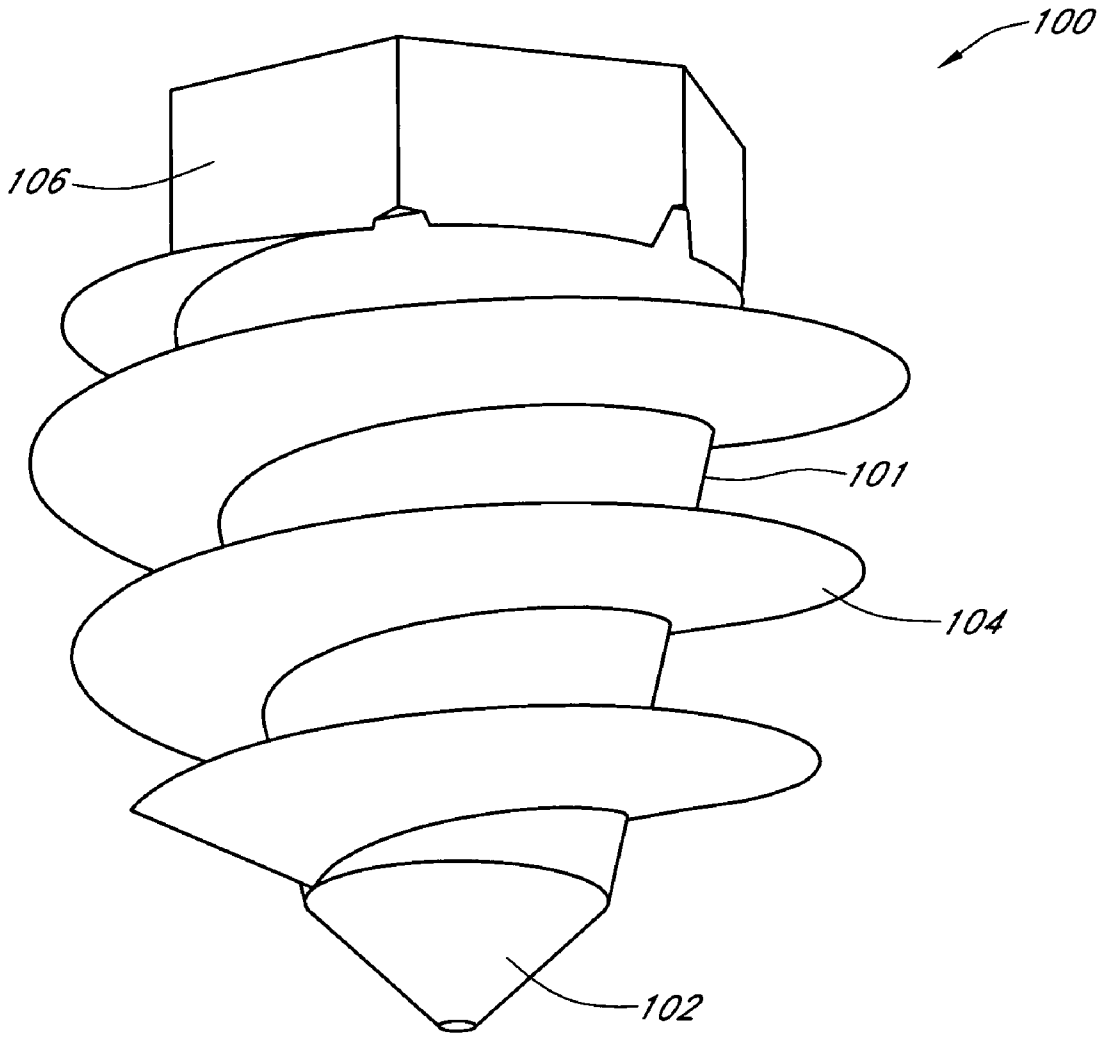

FIG. 4A

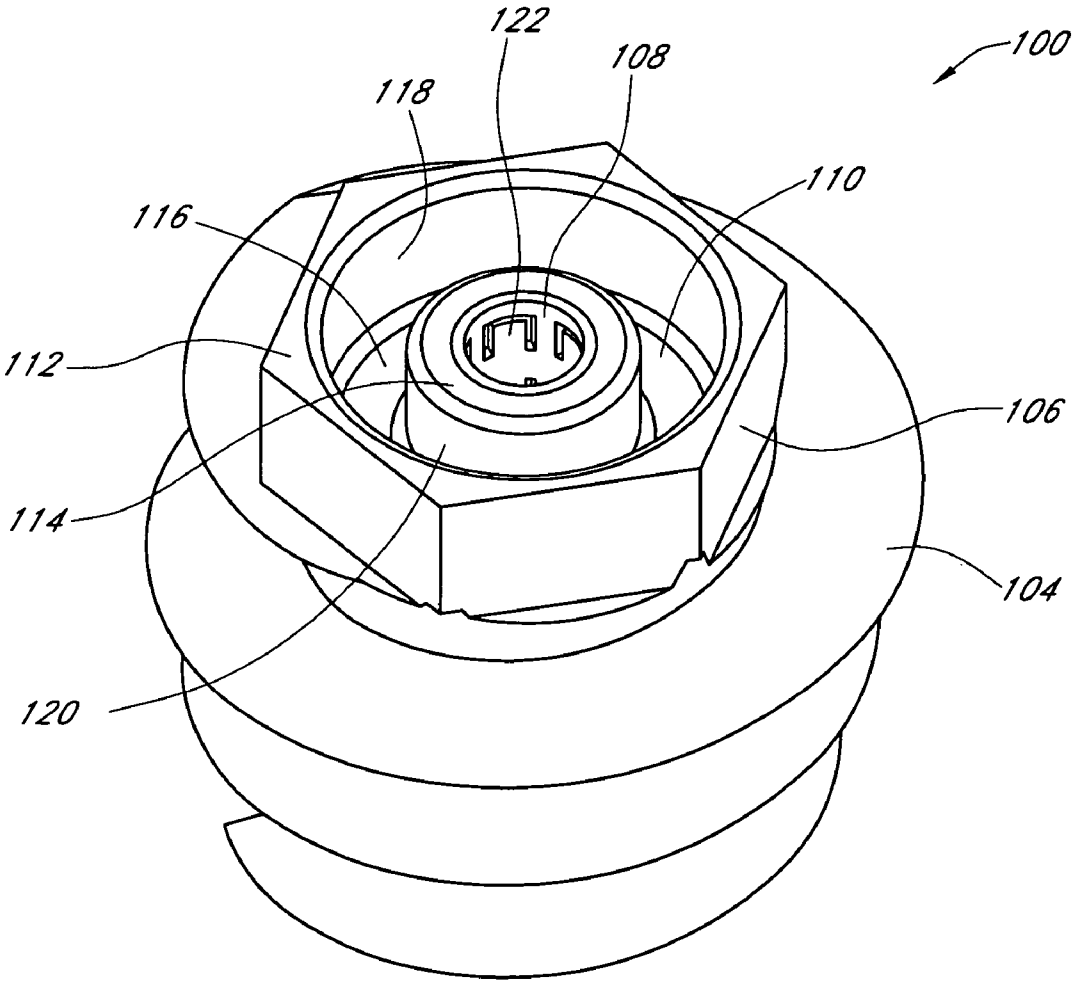

FIG. 4B

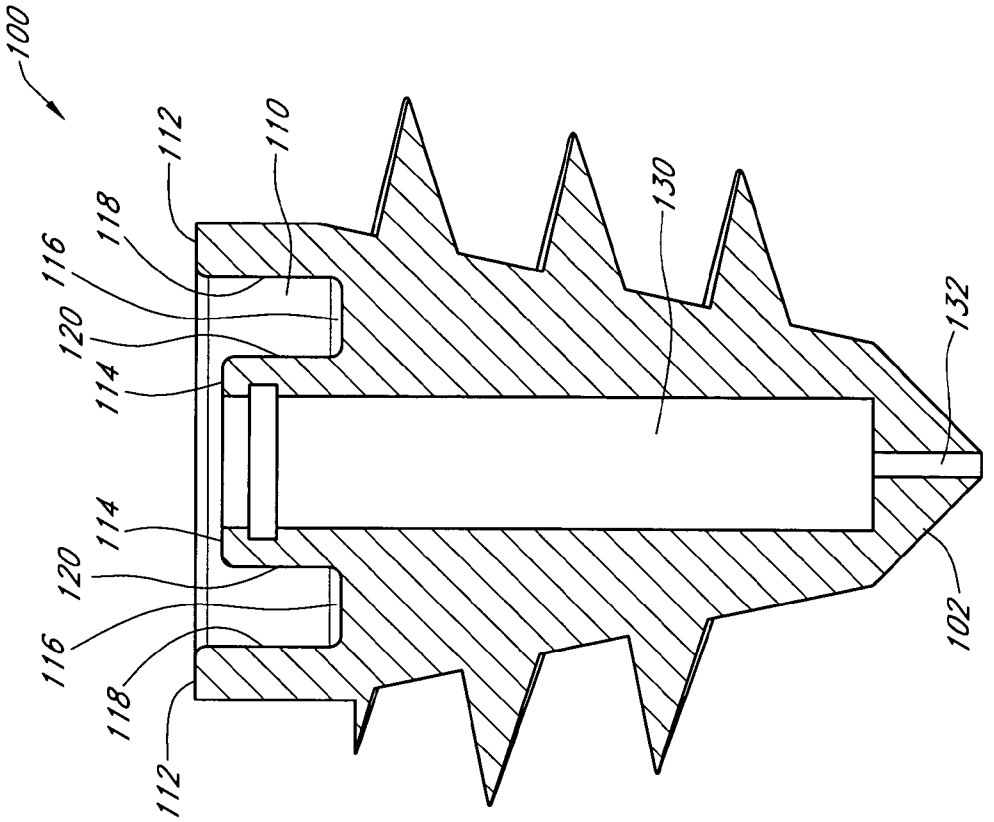
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FIG. 4D

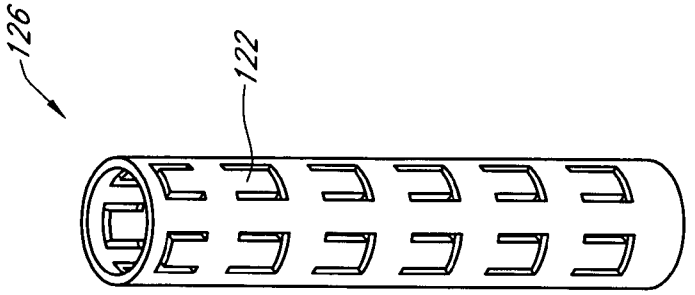
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FIG. 4C

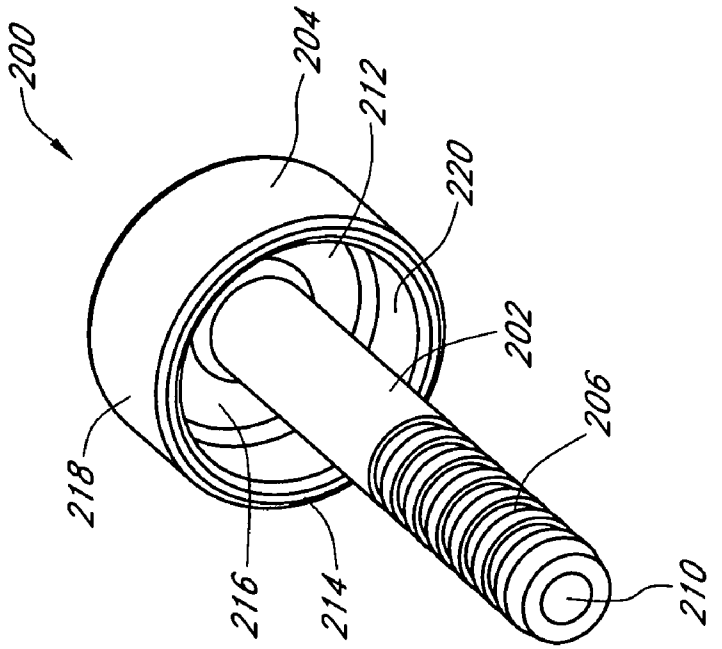


FIG. 5B

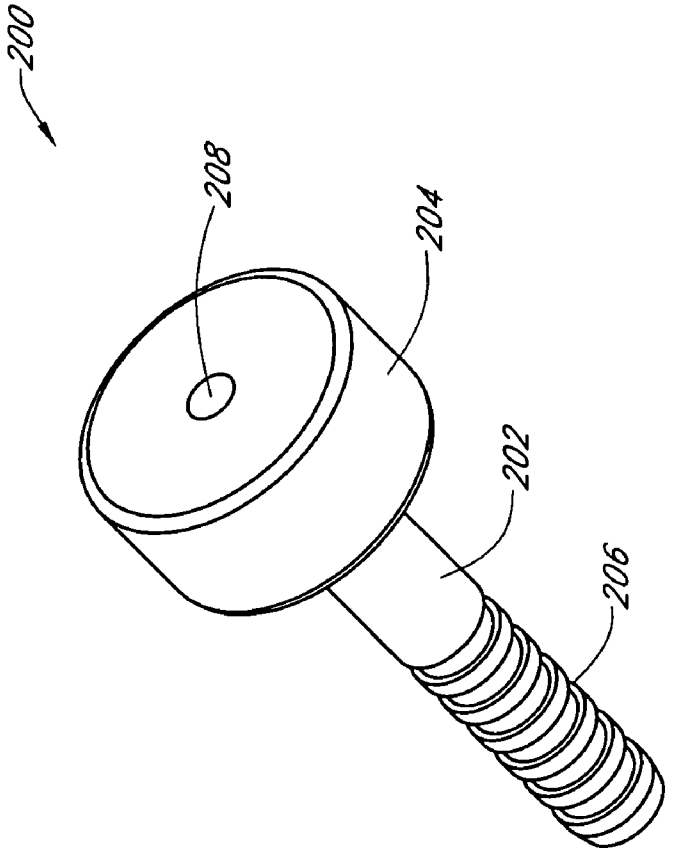
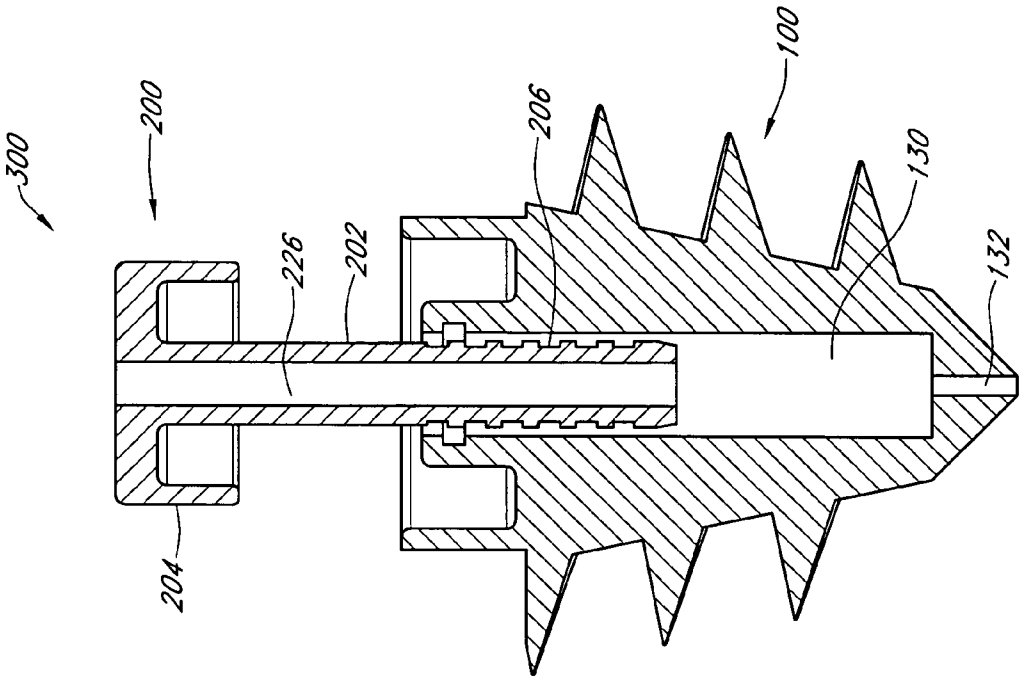


FIG. 5A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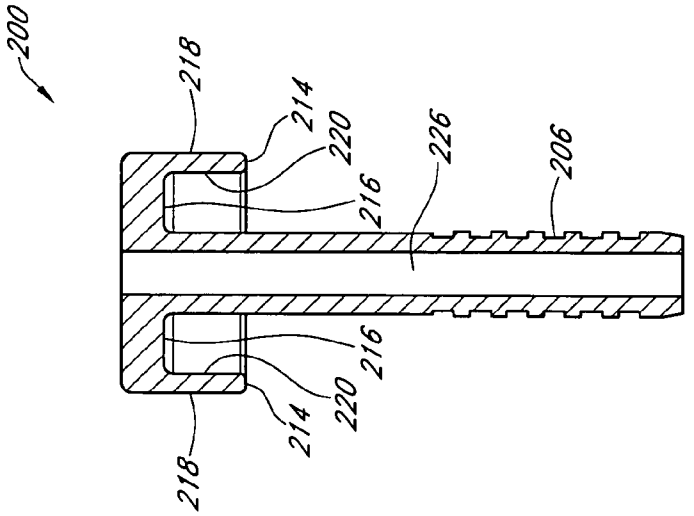
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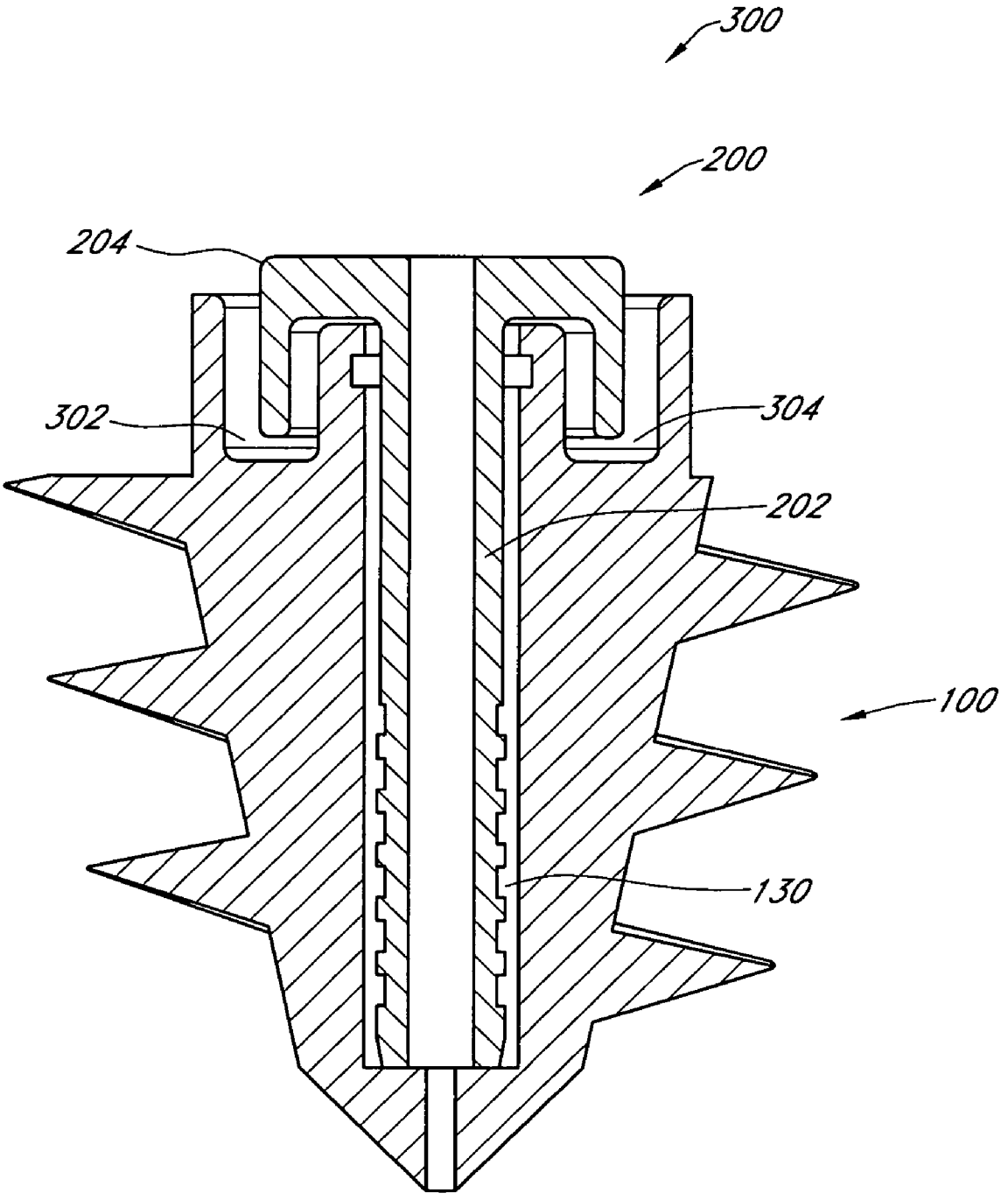

FIG. 6B

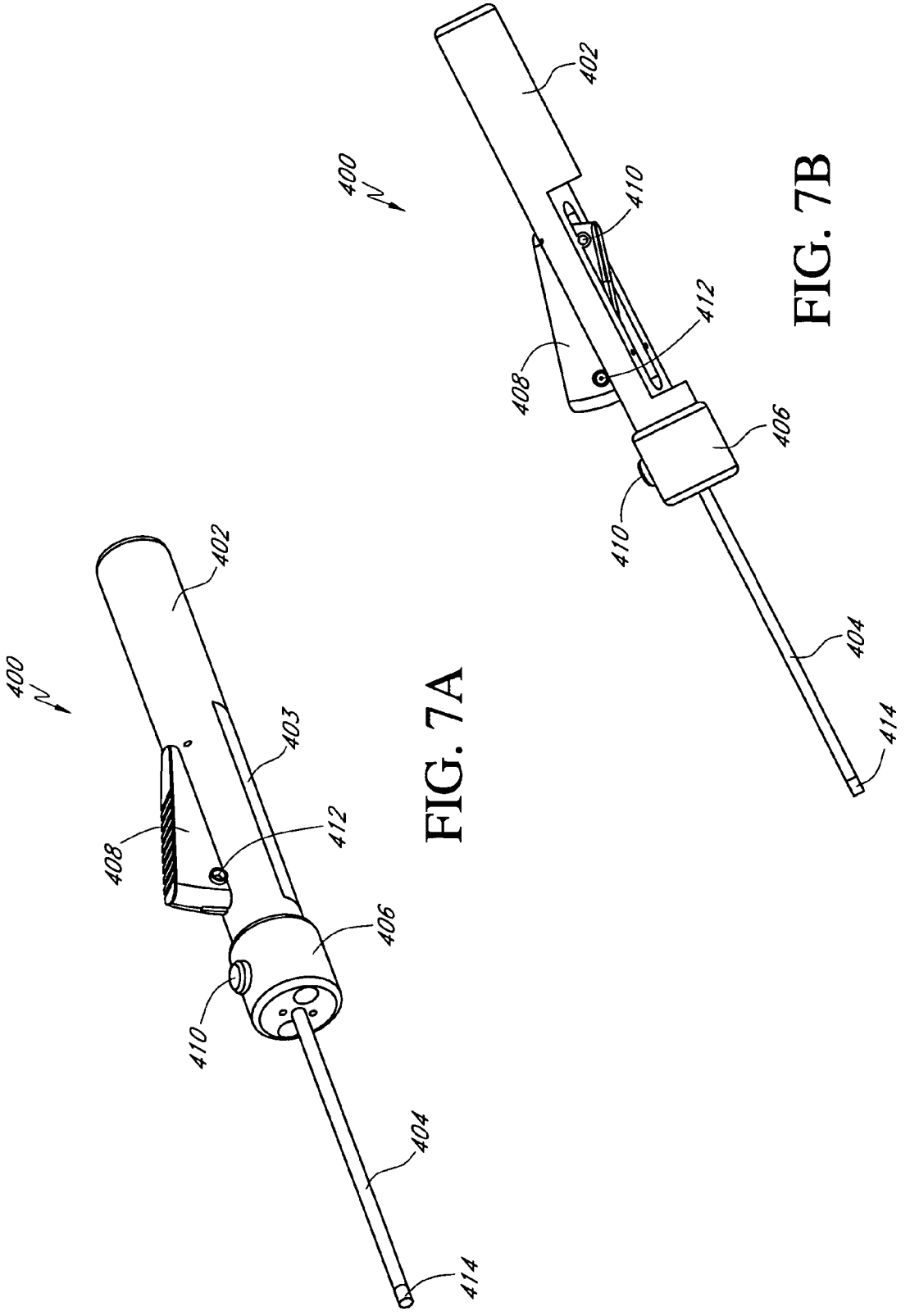
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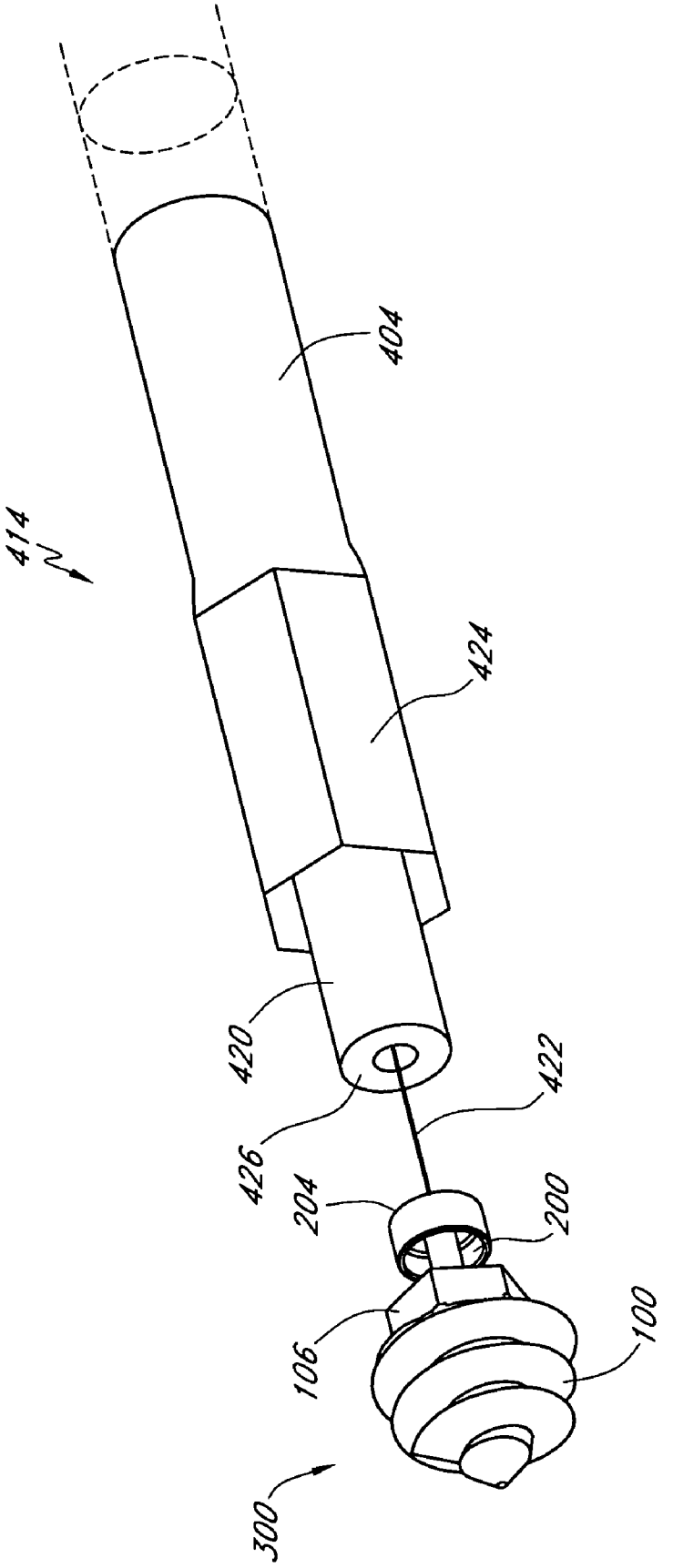
FIG. 7A

FIG. 7B



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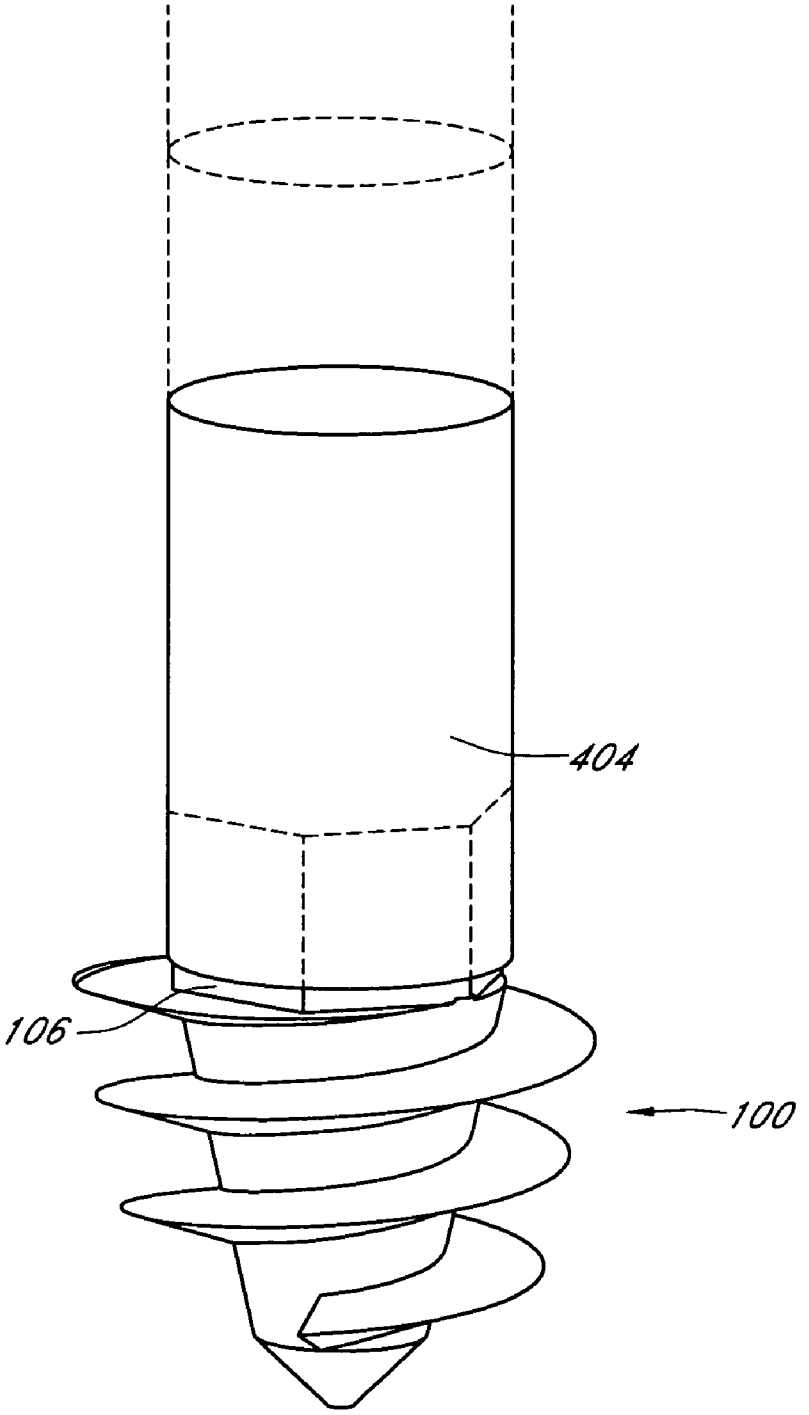


FIG. 9A

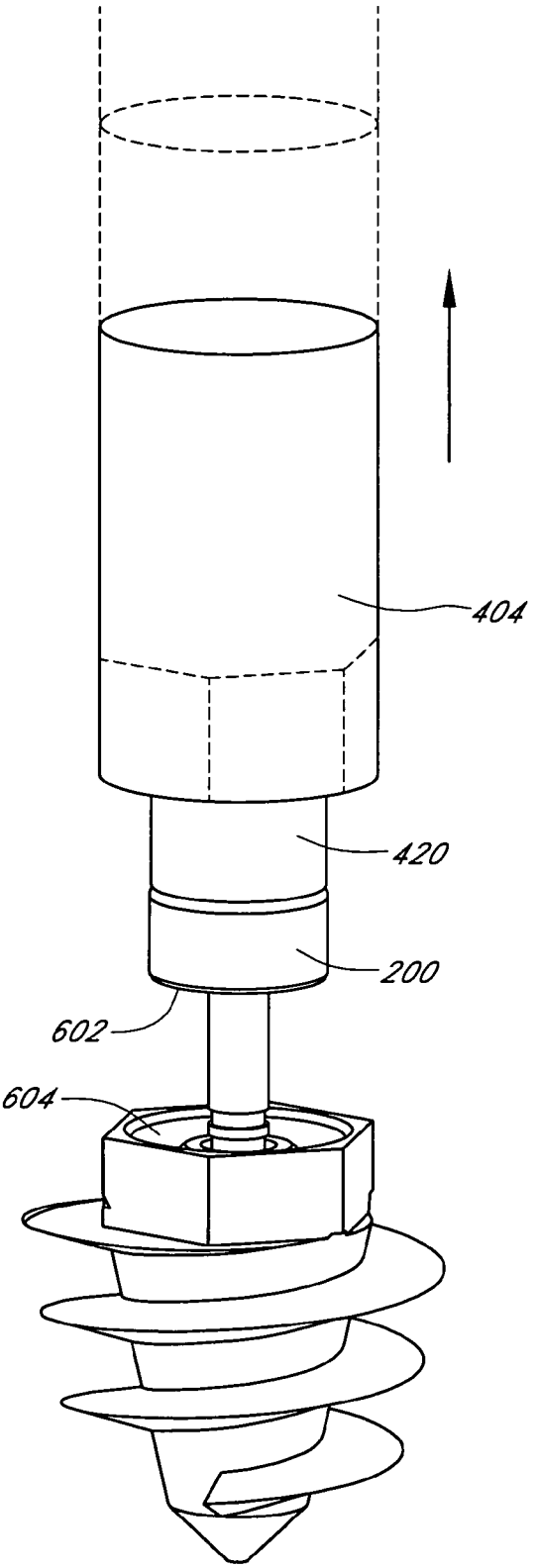


FIG. 9B

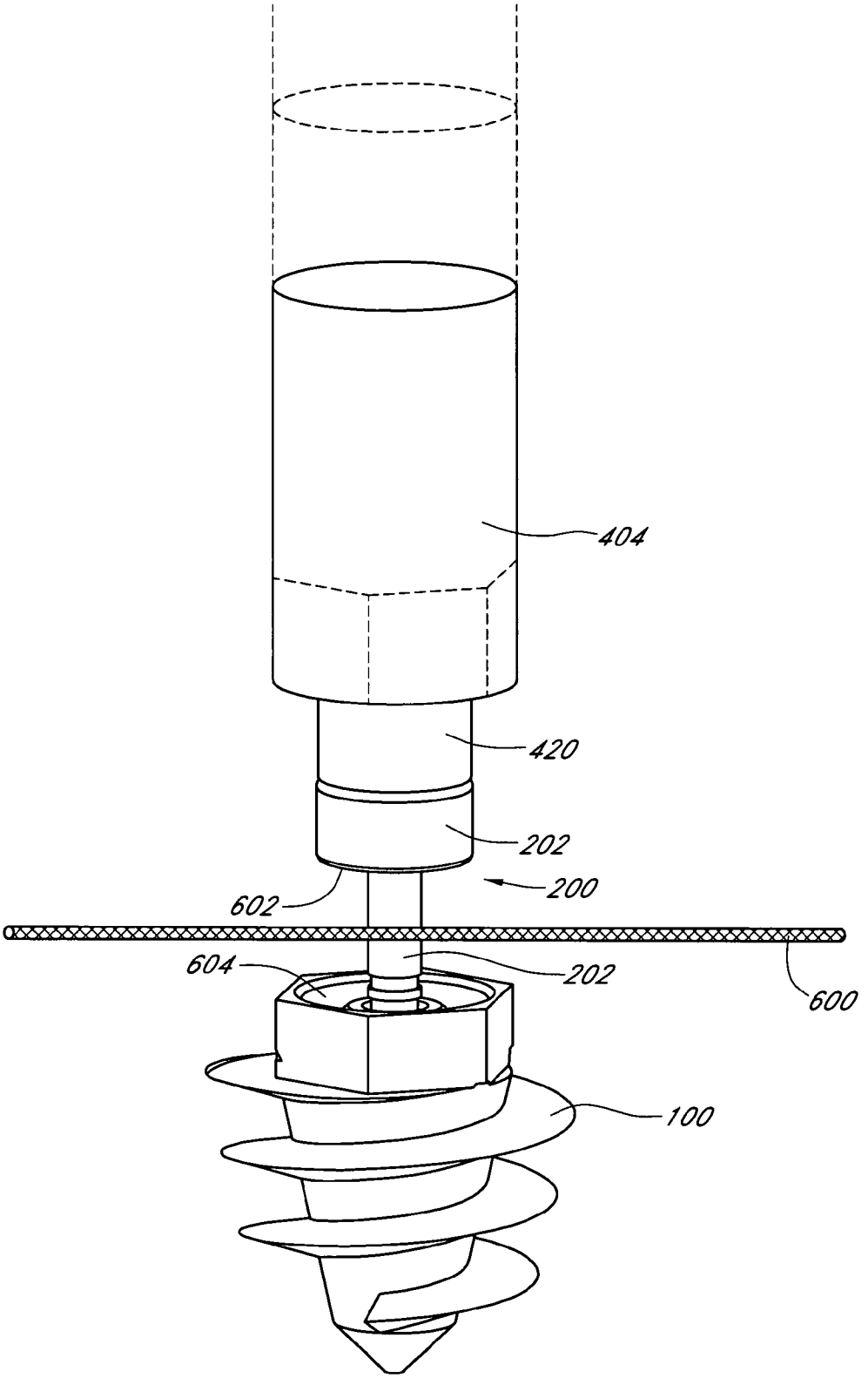


FIG. 9C

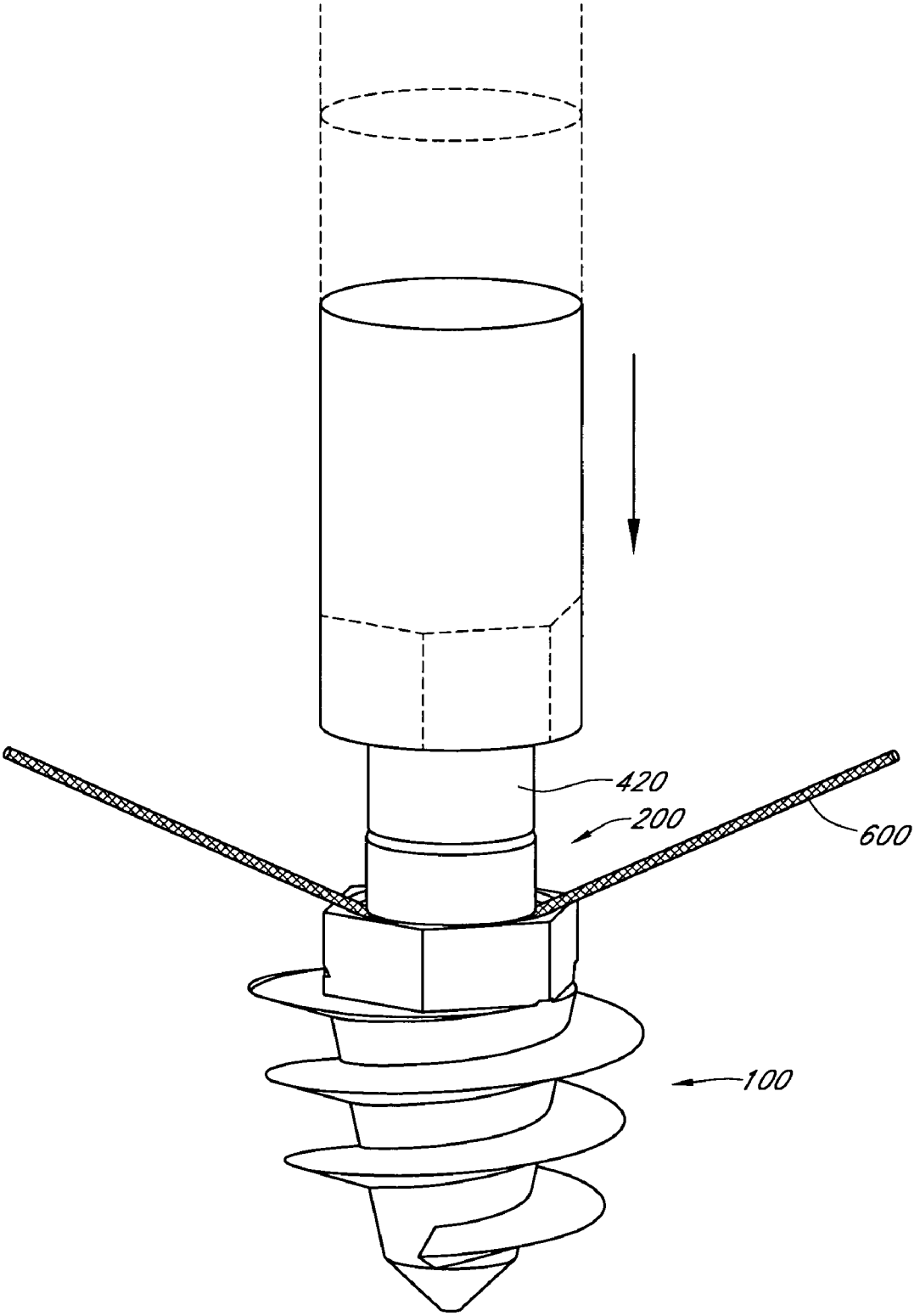


FIG. 9D

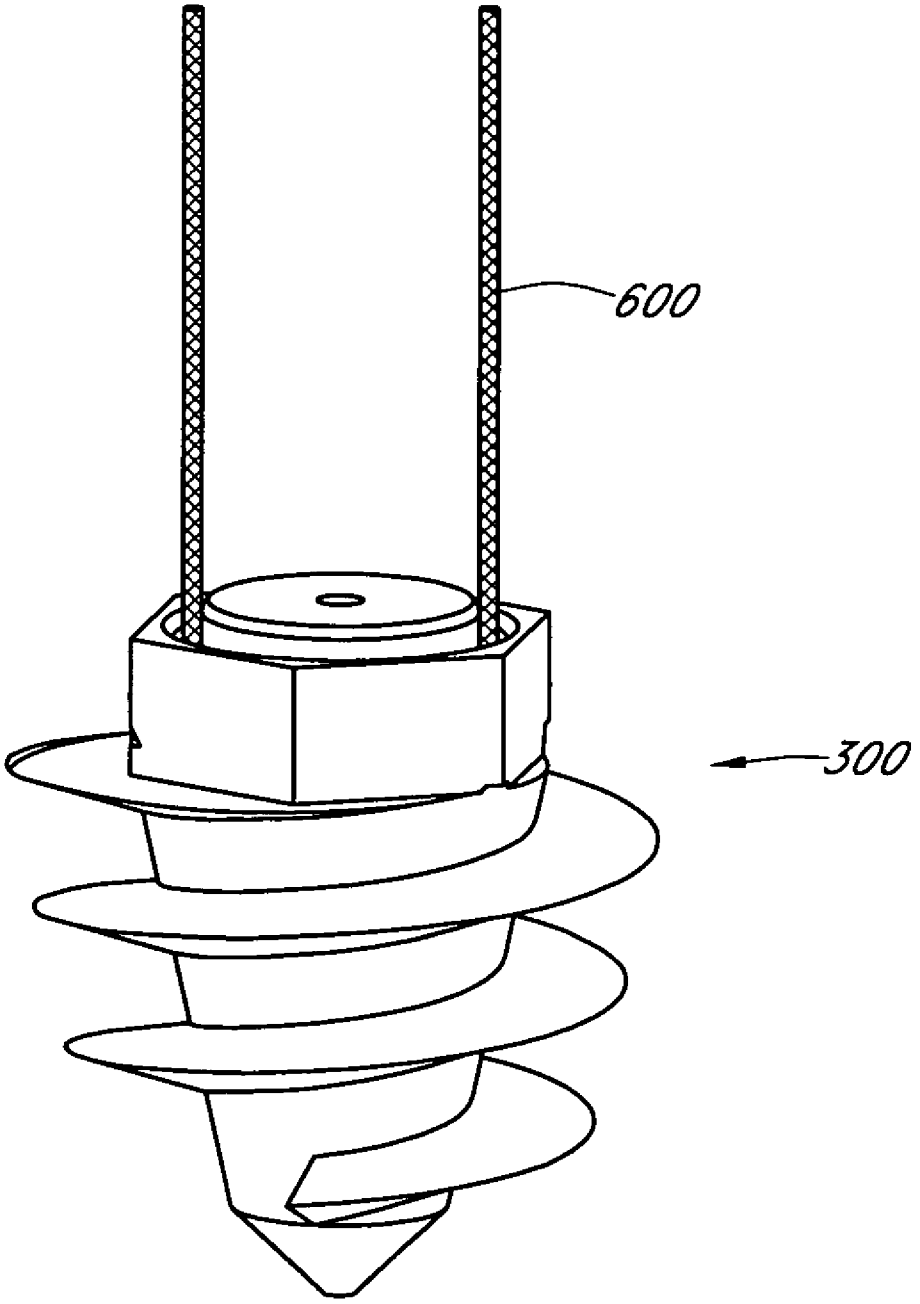


FIG. 9E

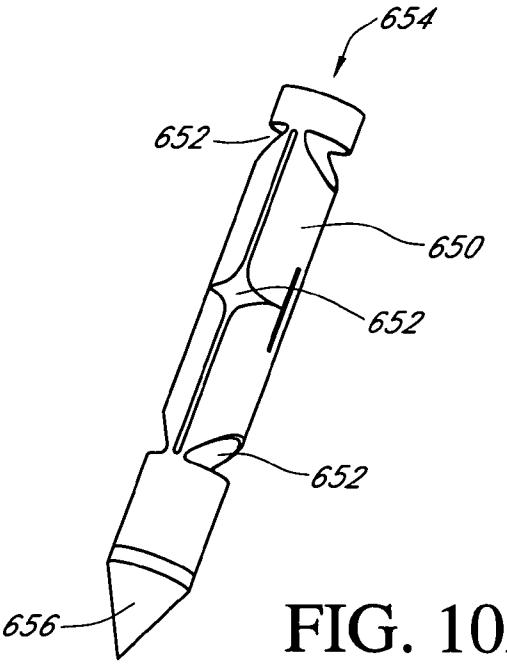


FIG. 10A

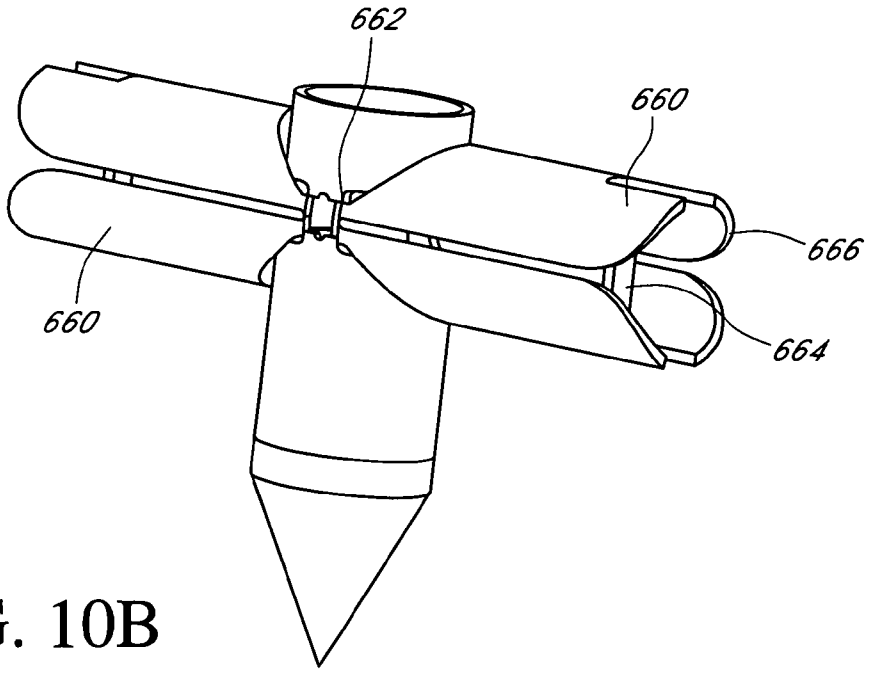
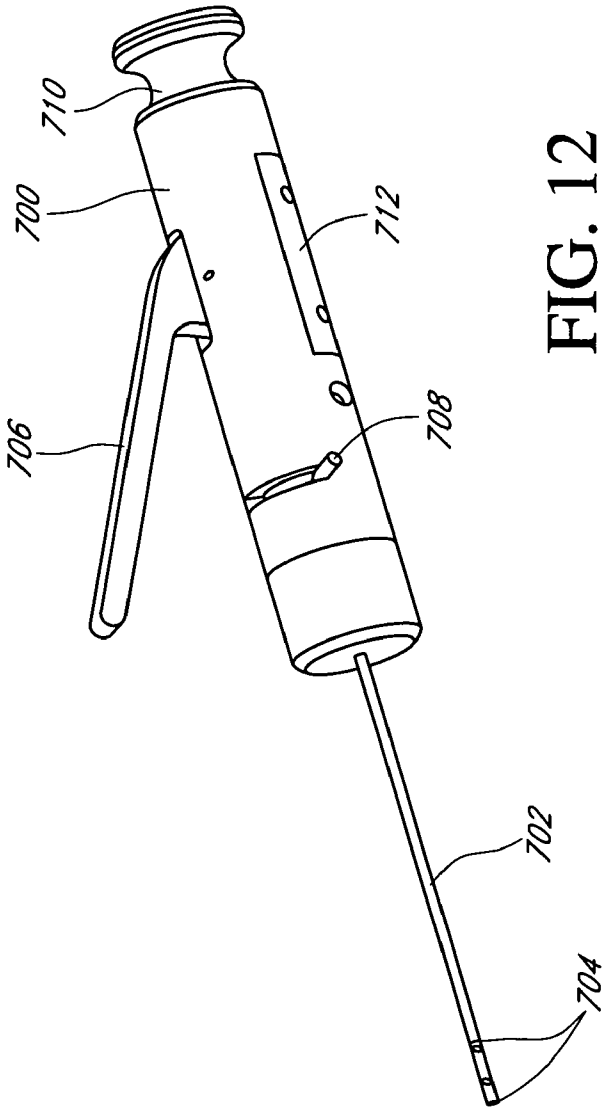


FIG. 10B



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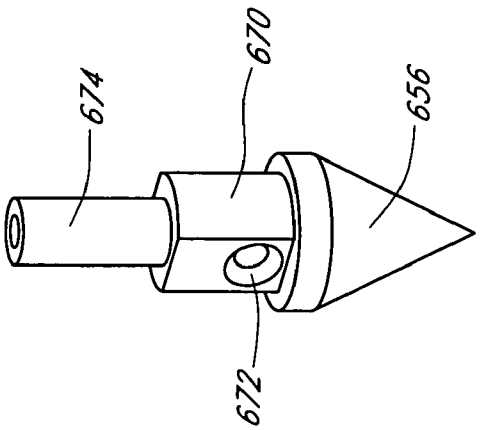

FIG. 11

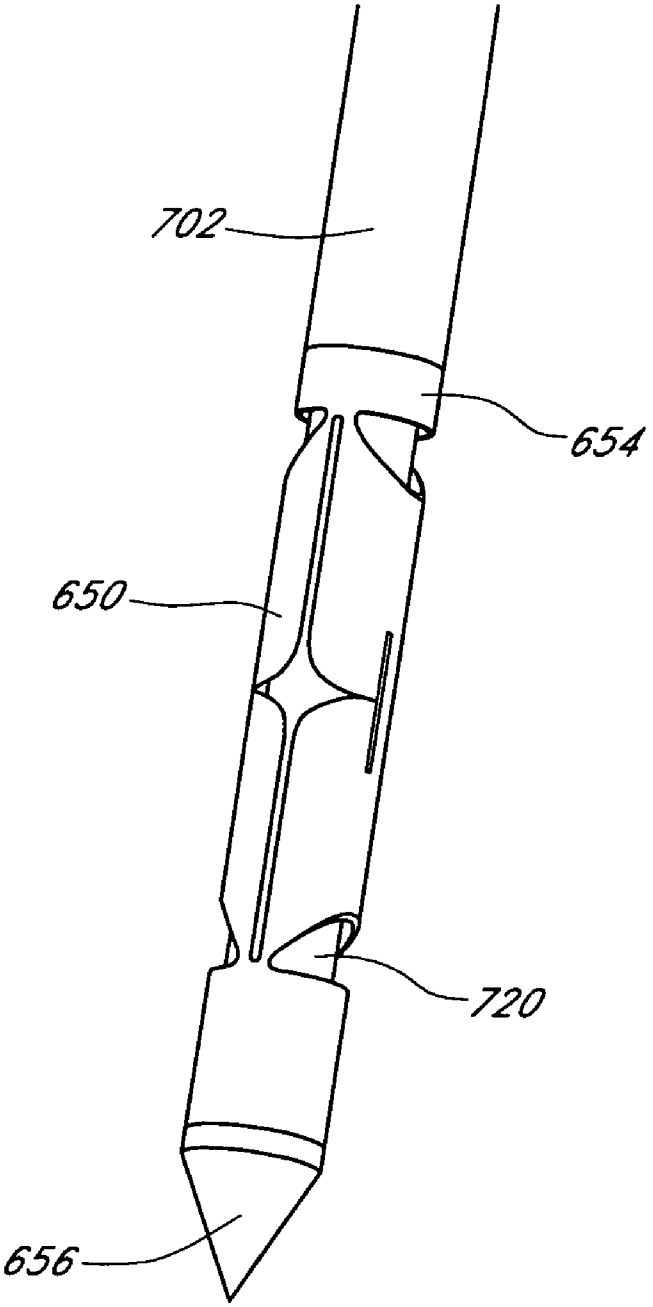

FIG. 13

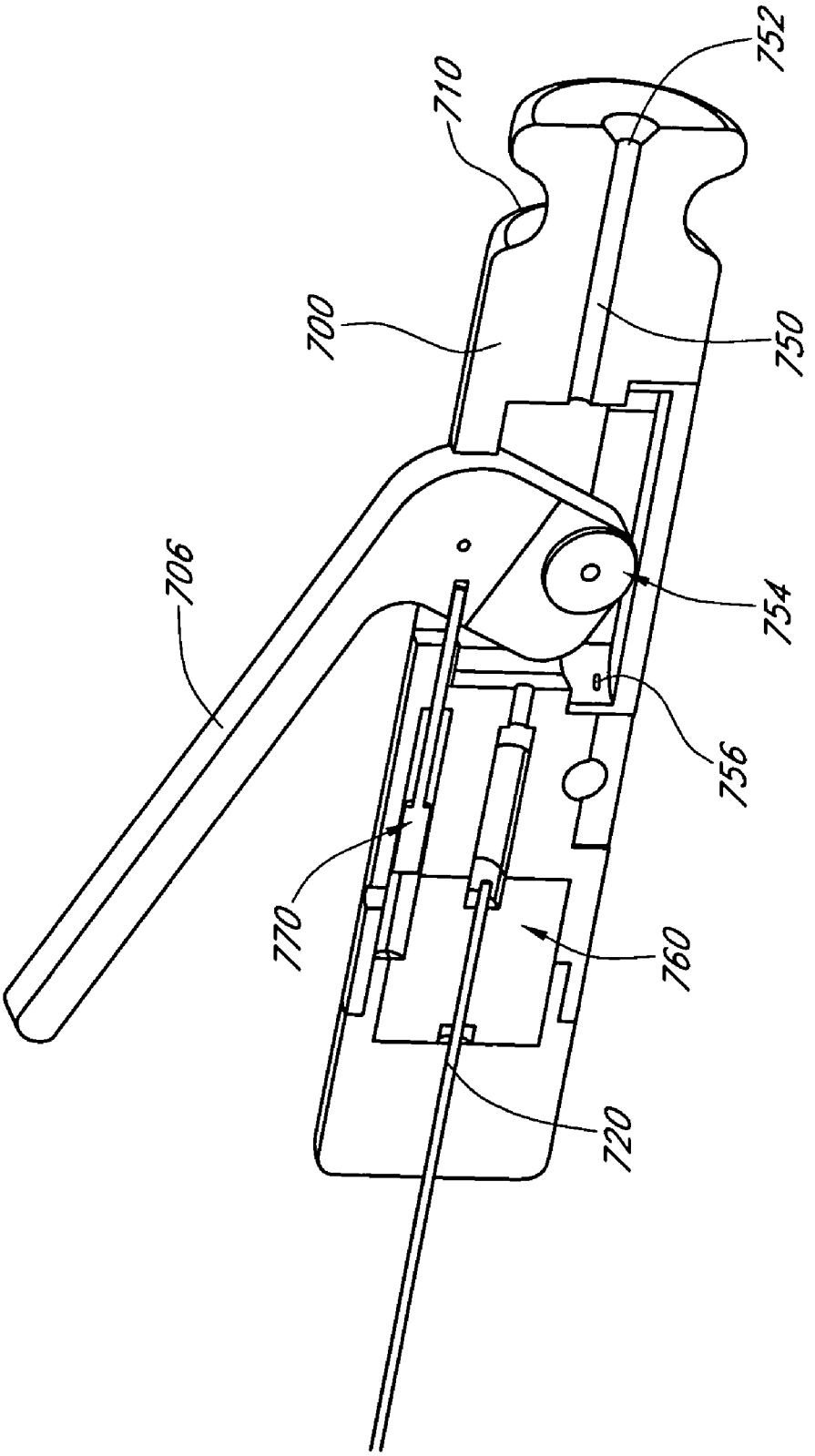

FIG. 14

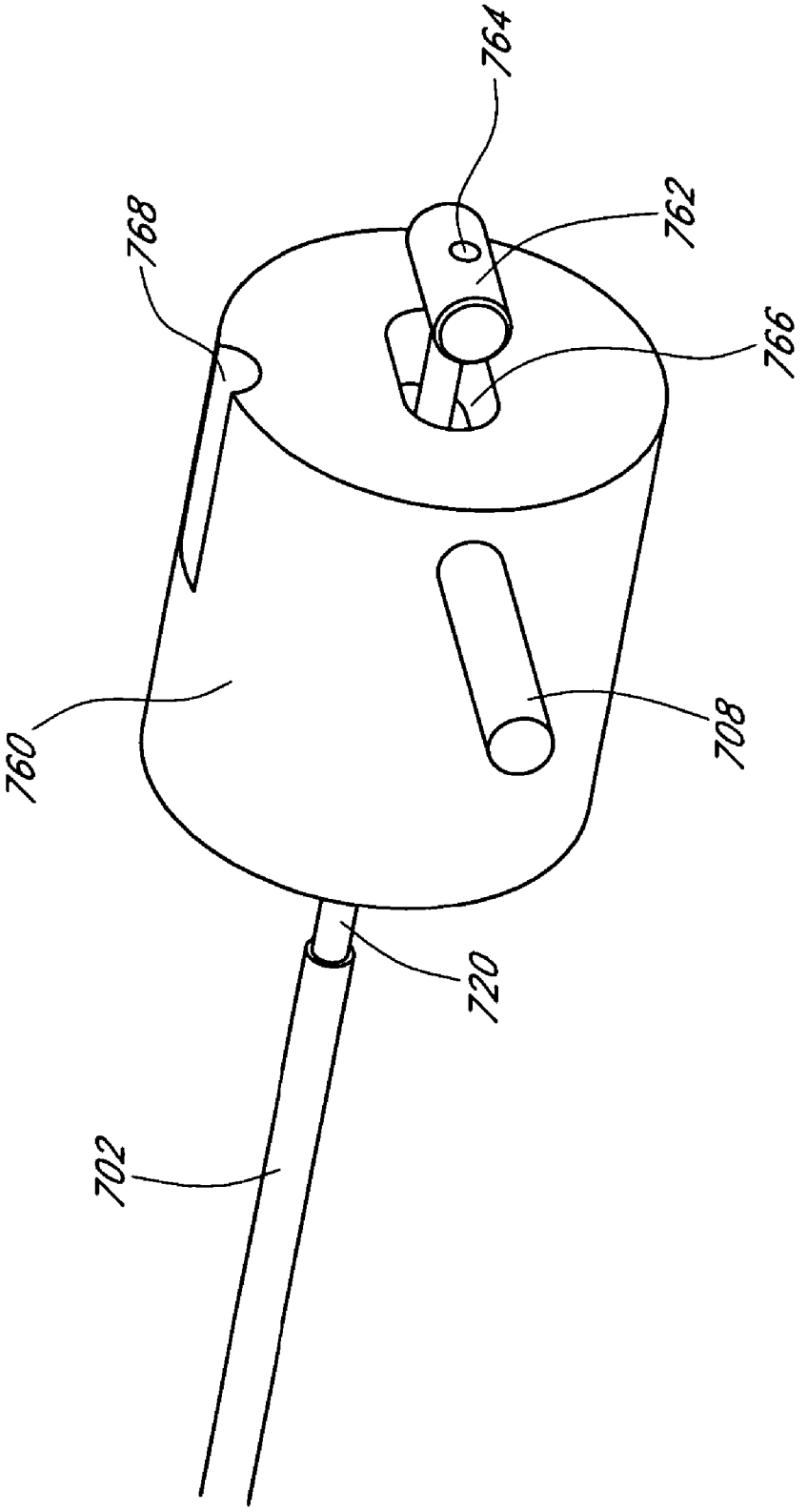

FIG. 15

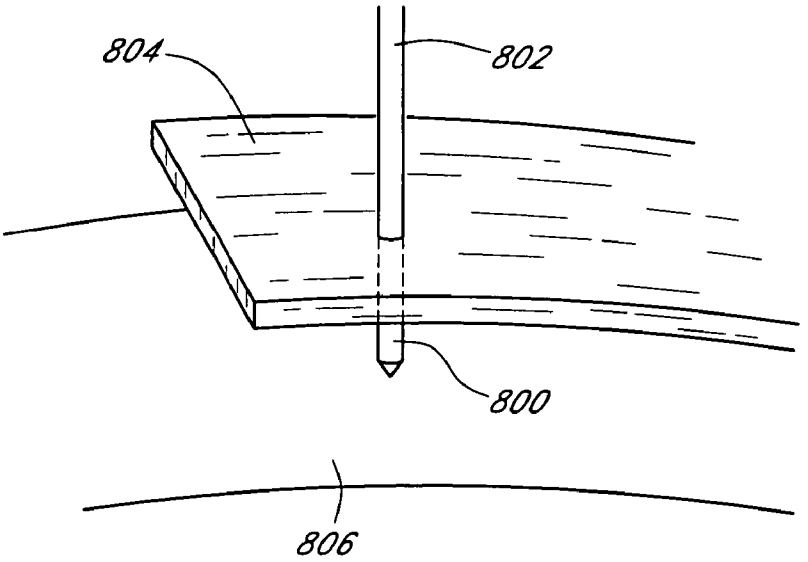

FIG. 16A

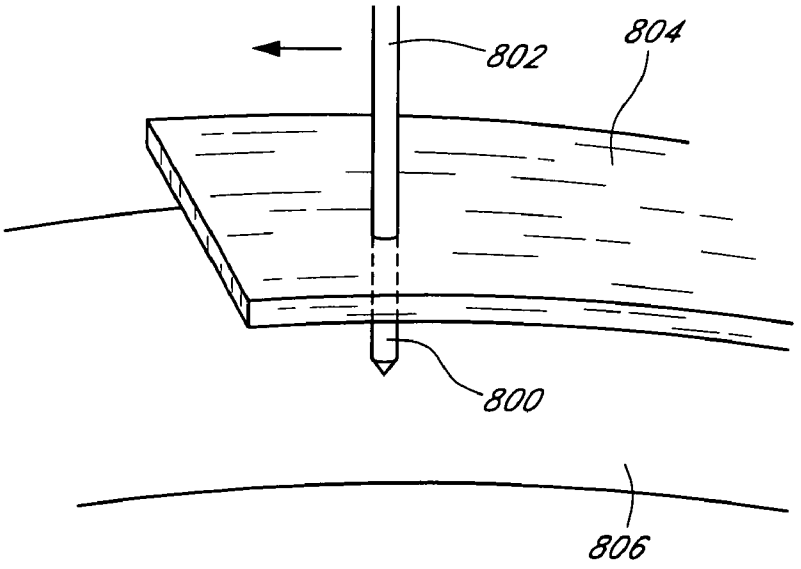

FIG. 16B

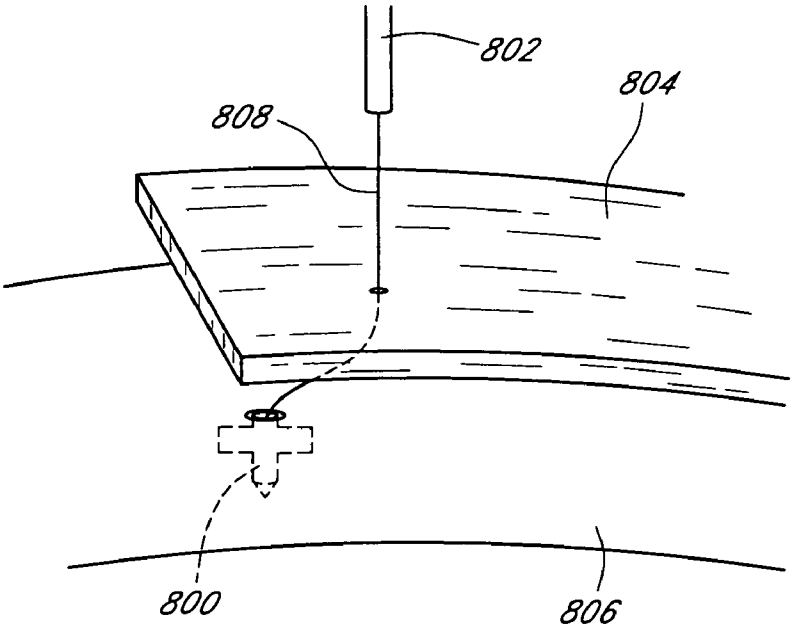

FIG. 16C

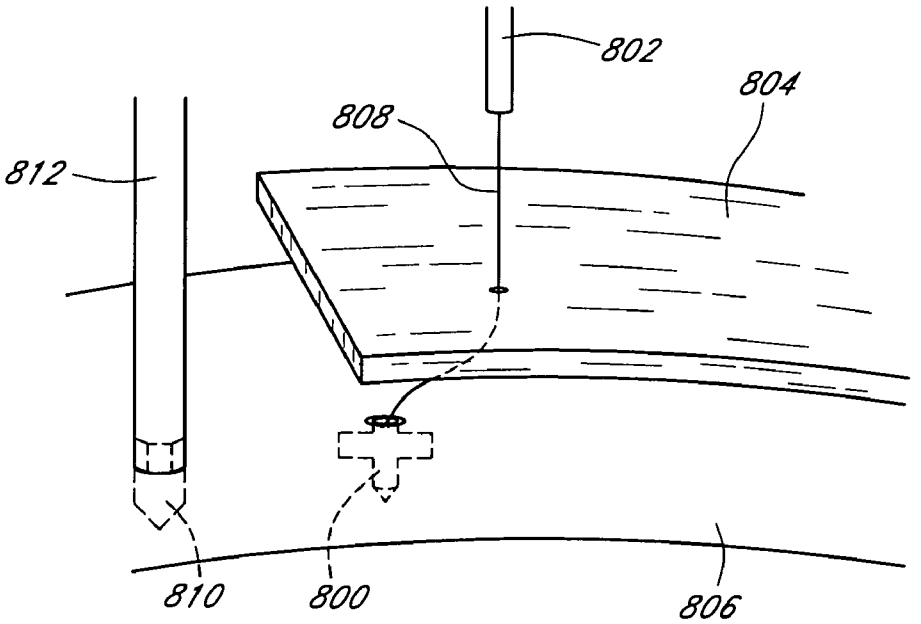

FIG. 16D

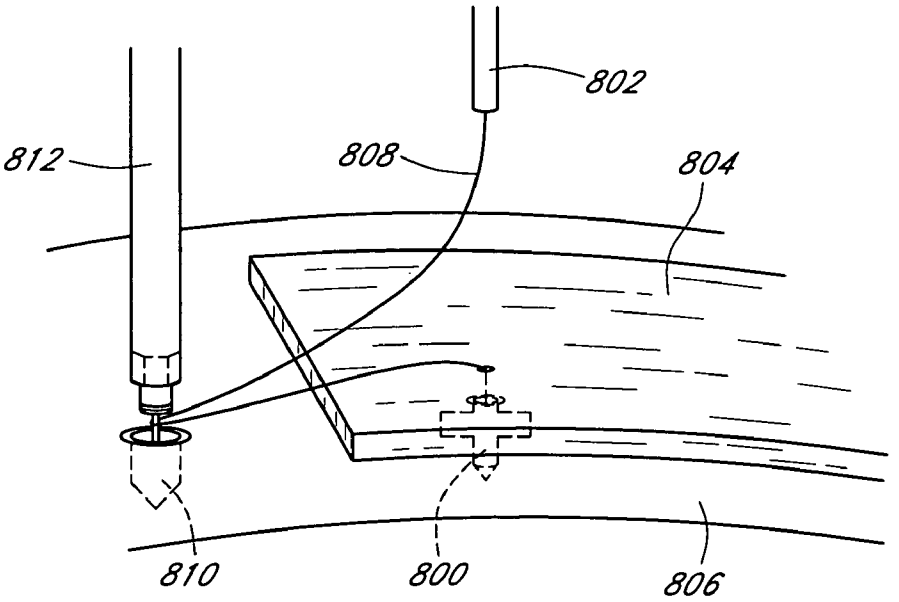

FIG. 16E

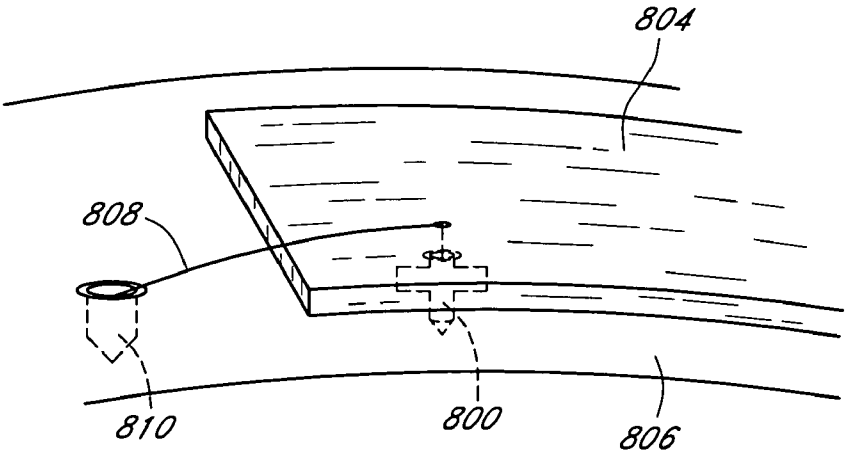

FIG. 16F

SYSTEM AND METHOD FOR ATTACHING SOFT TISSUE TO BONE

RELATED APPLICATIONS

This application claims priority to U.S. Provisional Application Nos. 60/576,477, filed on Jun. 2, 2004; 60/610,924, filed on Sep. 17, 2004; and 60/634,174, filed on Dec. 7, 2004; all of which are incorporated herein by reference in their entirety.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to medical devices and procedures. More particularly, the present invention relates to devices and methods for securing soft tissue to a rigid material such as bone.

2. Description of the Related Art

There are several medical procedures where a surgeon needs to attach soft tissue such as tendons or other soft connective tissue to bone. One common example is a torn rotator cuff, where the supraspinatus tendon has separated from the humerus causing pain and loss of ability to elevate and externally rotate the arm. To repair a torn rotator cuff, typically a surgical procedure is used to suture the torn tendon to the bone using a variety of methods. Some procedures utilize large incisions and involve complete detachment of the deltoid muscle from the acromion. Small diameter holes are made in the bone for passing suture material through the bone to secure the tendon. Such large incision procedures are traumatic, causing prolonged pain and recovery time. Other procedures make small incisions and use arthroscopic techniques to attach sutures using either small diameter holes or a bone anchor. However, it is difficult to manipulate sutures within the surgical site using arthroscopic techniques. In addition, when knot tying is used to secure the suture to a bone anchor, it is difficult to properly adjust the tension of the suture while tightening the knot. Similarly, when the suture is attached to a bone anchor prior to insertion of the anchor into the bone, it is difficult to judge the appropriate point of attachment so that the suture will be properly tensioned upon insertion of the bone anchor into the bone. Thus, there is a need for methods and devices that allow easy arthroscopic attachment of a suture to a bone anchor after the anchor is inserted into the bone without the use of knot tying.

SUMMARY OF THE INVENTION

The present invention is particularly suited for use in arthroscopic procedures, including but not limited to rotator cuff surgery. More broadly, it can be used in any procedure in which it is desired to fix a suture to a solid object without tying of knots, including not only arthroscopic procedures, but also open surgery, and can be used for such diverse purposes as bladder neck suspension, tendon and ligament affixation or repair, prosthetic attachment, and rotator cuff repair.

In one embodiment, the invention includes an anchor for securing a suture to bone, including an anchor base adapted to be securely fixed into the bone and a suture securing mechanism coupled to the anchor base and positioned proximally relative to the anchor base, the mechanism adapted to receive and secure a suture moved laterally into the

In another embodiment, the invention includes an anchor for securing a suture to bone, including an anchor base adapted to be securely fixed into the bone, a first surface coupled to the anchor base and positioned proximally relative

to the anchor base, and a second surface coupled to the anchor base and positioned proximally relative to the anchor base, wherein the first and second surfaces are adapted to be relatively positioned in at least two configurations, one of the configurations such that a gap is present between the first and second surfaces so that the suture can be positioned between the first and second surfaces by moving the suture laterally into the gap, and the other of the configurations such that the first and second surfaces are in close proximity so that the suture can be securely clamped between the first and second surfaces.

In another embodiment, the invention includes a method of attaching soft tissue to bone, including passing a length of suture over the soft tissue, inserting an anchor into the bone, and securing the length of suture to the anchor after the inserting without passing an end of the length of suture through any aperture in the anchor and without tying any knots.

In another embodiment, the invention includes a method of attaching soft tissue to bone, including inserting a first anchor through the soft tissue, wherein the first anchor comprises a length of suture fixedly secured to the first anchor prior to insertion, inserting the first anchor into the bone, passing the length of suture over the soft tissue, and fixedly securing, after the passing, the length of suture to a second anchor.

In another embodiment, the invention includes a method of attaching soft tissue to bone, the soft tissue comprising a first surface adjacent to the bone's surface and a second surface opposite the first surface, the method including inserting a first portion of a length of suture into the second surface of the soft tissue, passing a second portion of the length of suture over the second surface of the soft tissue, inserting a first anchor with no suture coupled thereto into the bone, and fixedly securing the length of suture to the inserted first anchor, with the proviso that no part of the first portion of the length of suture is passed out of the second surface of the soft tissue.

In another embodiment, the invention includes a method of attaching soft tissue to bone, including inserting a first anchor with a length of suture pre-coupled thereto through the soft tissue, inserting the first anchor into the bone, inserting a second anchor with no suture coupled thereto into bone, passing the length of suture over the soft tissue, and fixedly securing the length of suture to the inserted second anchor.

In another embodiment, the invention includes a method of attaching soft tissue to bone, the method including inserting a first, second, and third anchor into the bone, fixedly securing a first length of suture over the soft tissue to the first and second anchors, and fixedly securing a second length of suture over the soft tissue to the first and third anchors.

In another embodiment, the invention includes an anchor for securing a suture to bone, the anchor including an anchor base adapted to be securely fixed into the bone, the anchor base comprising a first proximal surface and an anchor top, the anchor top comprising a distal member coupled to the anchor base and a first proximal member comprising a first distal surface, wherein the anchor top is adapted to couple to the anchor base in at least two configurations, one of the configurations such that the first distal surface is above the bone's surface when the anchor base is securely fixed into the bone, such that a suture can be freely passed between the first proximal and first distal surfaces above the bone's surface, and the other of the configurations such that the first distal surface is in close proximity to the first proximal surface, such that a suture can be securely clamped between the first proximal and first distal surfaces.

In another embodiment, the invention includes an anchor for securing a suture to bone, the anchor including a substantially hollow cylinder comprising an open end and comprising a portion of its walls cut in such a manner so as to allow the cylinder to deform under stress and form lateral protrusions, a substantially pointed tip coupled to the cylinder opposite the open end, wherein the pointed tip is adapted to pierce the bone, and a suture receiver coupled to the pointed tip and positioned within the substantially hollow cylinder so that a suture may be attached to the suture receiver and extend through the cylinder and out of the open end.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** depicts attaching soft tissue to bone using a single bone anchor and a stitch.

FIG. **2** depicts attaching soft tissue to bone using a two bone anchors with a suture stretched there between.

FIGS. **3**A-**3**C depict various geometries of bone anchors and suture patterns for attaching soft tissue to bone.

FIGS. **4**A-**4**D depicts the base of a two-part suture anchor that can be inserted into bone.

FIGS. **5**A-**5**C depicts the top of a two-part suture anchor.

FIGS. **6**A and **6**B depict the suture anchor top of FIGS. **5**A-**5**C inserted into the suture anchor bottom of FIGS. **4**A-**4**D.

FIGS. **7**A and **7**B depict a suture anchor inserter.

FIG. **8** depicts components on a suture anchor inserter for attaching to bone and manipulating a suture anchor.

FIGS. **9**A-**9**E depicts manipulation of a suture anchor using a suture anchor inserter to insert the suture anchor into bone and attach suture material to the suture anchor.

FIGS. **10**A and **10**B depict a piercing bone anchor in an un-deployed (FIG. **10**A) and deployed (FIG. **10**B) state.

FIG. **11** depicts a piercing bone anchor tip.

FIG. **12** depicts an anchor inserter for inserting a piercing bone anchor.

FIG. **13** depicts the interface between a piercing bone anchor and an anchor inserter.

FIG. **14** is a cut-away view of a bone anchor inserter.

FIG. **15** depicts a safety switch mechanism for a bone anchor inserter.

FIGS. **16**A-**16**F depict a method for attaching soft-tissue to bone using a piercing bone anchor and a suture capturing anchor.

DETAILED DESCRIPTION OF THE CERTAIN EMBODIMENTS

In various embodiments, soft tissue may be attached to bone utilizing one or more bone anchors with suture attached thereto. As used herein, "suture" refers to any flexible structure that can be stretched between two or more anchors and includes, without limitation, traditional suture material, single or multiple stranded threads, or a mesh structure. In some embodiments, suture is passed over the top of the soft tissue so that the suture can press the soft tissue against the bone. In one embodiment, a length of suture is attached to a single bone anchor. One non-limiting example, depicted in FIG. **1**, includes stitching the suture **10** to the soft tissue **12**, such as by an incline mattress stitch, and then securing the suture **10** to the single bone anchor **14** that is inserted into the bone **16**. However, in other embodiments, a length of suture is attached to multiple bone anchors. The use of multiple bone anchors increases the footprint over which the suture material presses the soft tissue against bone. One non-limiting example, depicted in FIG. **2**, includes two bone anchors. One anchor **20** is positioned in a medial location underneath the soft tissue **12** and a second anchor **22** is positioned lateral to the soft tissue **12**. The suture **10** is attached to both anchors.

In one embodiment, the suture **10** is attached to the lateral bone anchor **22** only after the medial bone anchor **20** is inserted and the suture **10** is passed over the soft tissue **12**. In one embodiment, the suture **10** is attached to the medial bone anchor **20** prior to insertion of the medial bone anchor **20**. Thus, in this embodiment, the surgeon does not need to pass the suture through the soft tissue **12** from beneath the soft tissue **12**. In one embodiment, the procedure involves inserting the medial bone anchor **20** with suture **10** pre-attached through the soft tissue **12**. The medial bone anchor **20** may then be moved laterally relative to the bone **16** in order to pull the soft tissue **12** laterally relative to the bone **16**. After appropriate positioning of the soft tissue **12**, the medial bone anchor **20** may then be inserted into the bone **16**. The lateral bone anchor **22** may then be inserted into the bone **16**. The suture **12** may then be passed over the soft tissue **12** and attached to the lateral bone anchor **22**. In some embodiments, a lateral bone anchor **22** is provided to which suture **12** can be attached without tying any knots or without passing the suture **12** through any aperture in the lateral bone anchor **22**.

In some embodiments, multiple anchors and multiple suture lengths may used to provide a wider area of pressure of the soft tissue against bone. For example, as depicted in FIG. **3**A, three anchors are used with two lengths of suture **26** and **28**. Alternatively, a mesh structure **29** may be stretched between the three anchors. In another example, as depicted in FIG. **3**B, four anchors are used with two lengths of suture. In still another example, as depicted in FIG. **3**C, four anchors are used with four lengths of suture. In some embodiments, the individual suture lengths may be part of a larger continuous suture. For example, in FIG. **3**A, the suture lengths **26** and **28** may be part of a larger length of suture such that the lengths **26** and **28** are joined at medial bone anchor **20**. Those of skill in the art will appreciate that there are any number of anchor and suture geometries that can be used.

In some embodiments, the medial bone anchors **20** are designed so that they can be easily pierced through the soft tissue **12** and bone **16**. In some embodiments, the lateral bone anchors **22** are designed so that they can easily capture suture material after insertion of the bone anchors **22**. Together, these design features provide a suturing system and method that provides an increased footprint of suture pressure against the soft tissue **12** and ease of implementation for a surgeon. For example, in some embodiments, the entire procedure may be done arthroscopically, with the surgeon needing only to insert the medial bone anchor **20** with suture optionally pre-attached through a first port, insert the lateral anchor **22** through a second port, pass the suture over the soft tissue **12** by capturing it from within the second port, and securing the suture to the lateral anchor **22**. Accordingly, described below are certain embodiments of anchors adapted to capture suture material and anchors adapted to easily pierce through soft tissue and bone.

Suture Capturing Anchor

One embodiment is a bone anchor that allows easy capturing and securing of a suture after the bone anchor is inserted into the bone. In one embodiment, the bone anchor includes a suture securing mechanism positioned on the proximal end of the bone anchor (i.e., the end nearest the surface of the bone and the surgeon). In one embodiment, the suture securing mechanism allows a suture to be moved laterally into the mechanism. By "laterally," it is meant that the suture can be moved into the mechanism by moving the suture in a direc-

tion that is generally perpendicular to the axis of the suture. In other words, the suture can be moved into the mechanism without threading an end of the suture into the mechanism. In one embodiment, the suture can be fixedly secured within the mechanism without tying any knots. By "fixedly secured," it is meant that the suture within the securing mechanism cannot be easily moved relative to the bone anchor.

One embodiment is a bone anchor that allows easy attachment of suture material by clamping the suture material between two surfaces on the bone anchor. The bone anchor may be configured such that the bone anchor is inserted into the bone without the suture material attached. The two surfaces of the suture securing mechanism may be spaced apart so as to form a gap between the surfaces. The suture material may be passed between the two surfaces and tensioned as desired followed by clamping of the two surfaces together, thereby clamping the suture material there between.

In one embodiment, the bone anchor consists of two parts: an anchor base and an anchor top. The anchor base may be designed to be inserted into a hole in the bone with a proximal surface facing up. The anchor top may be coupled to the anchor base via a distal member. A proximal member on the anchor top may have a distal surface facing down toward the proximal surface on the anchor base. The coupling of the anchor top to the anchor base may be such that the anchor top can move relative to the anchor base such that it can be positioned in one configuration where there is space between the proximal surface on the anchor base and the distal surface on the proximal member of the anchor top. In another configuration, the proximal member of the anchor top may be position such that there is very little space, if any, between the proximal surface on the anchor base and the distal surface on the proximal member of the anchor top. Thus, in the first configuration, suture material may be easily passed between the two surfaces and tensioned as desired. In the second configuration, the suture material may be clamped between the two surfaces such that the suture is secured to the bone anchor.

One embodiment of an anchor base **100** is depicted in FIGS. **4**A through **4**D. FIG. **4**A is a perspective view showing the side **101** and bottom **102** of the anchor base **100**. The bottom **102** of the anchor base **100** may advantageously be tapered to facilitate insertion of the anchor base **100** into bone. In some embodiments, a hole is predrilled into the bone to facilitate insertion of the anchor base **100**. In other embodiments, the anchor base **100** is forced directly into the bone, thereby creating the hole. The sides **101** of the anchor base **100** comprise threads **104** so that the anchor base **100** may be inserted into bone using a screwing action. In some embodiments, the anchor base **100** may be tapped to start the threads **104** into the bone followed by screwing the anchor base **100** into the bone. When the hole in the bone is pre-drilled, the hole is advantageously drilled with a diameter smaller than the diameter of threads **104** so that the threads engage the bone through the sides of the hole. It will be appreciated that means other than threads may be used to secure the anchor base **100** to bone. For example, angled protrusions may be used that provide greater resistance to removal of the anchor base **100** than to insertion. The protrusions may be static or deployable once the anchor is inserted.

The top of anchor base **100** preferably includes a structure **106** for facilitating the driving or screwing of the base **100** into the bone. In the illustrated embodiment, this comprises a hex nut structure **106** that facilitates engagement with a hex nut driver for screwing the anchor base **100** into the bone. It will be appreciated that other structures known in the art for engaging tools used for screwing action may be used instead of hex nut structure **106**, and that this structure can be indented into or extending out from the top of the anchor base **100**, or can alternatively be formed on the sides of the anchor base **100**.

With reference to FIG. **4**B, which is a perspective view of the top and side of anchor base **100**, the top (proximal end) comprises a hole **108** in the center for receiving the anchor top, which is described below. The top of anchor base **100** also contains a suture gripping structure such as a circular groove **110** that may be concentric with hole **108**. Because of groove **110**, the proximal surface of anchor base **100** is not flat and comprises top surfaces **112** and **114**, bottom surface **116**, and side surfaces **118** and **120**. In some embodiments, some or all of these surfaces may be textured such as with a scallop shape or grooves so as to inhibit movement of suture material pressed against the surfaces. Although a grooved surface is illustrated, it will be appreciated that other shapes for the proximal surface of anchor base **100** are also contemplated, including multiple concentric grooves, a series of protruding ridges, a "vee" shaped channel, or any other suitable structure that permits a suture to be securely locked against the top or proximal end of the anchor base **100**.

Hole **108** in anchor base **100** is an opening into a central ("axial") bore into the anchor base **100**. The sides of the central bore preferably include structures for gripping something inserted into the central bore, such as ratchet structures **122**. FIG. **4**C show a central ratchet bushing **126** that fits within the central bore and contains the ratchet structures **122**. In the embodiment of FIG. **4**C, the ratchet structures **122** are constructed by cutting U shaped cuts into bushing **126**. The U shaped cuts then define tabs that make up the ratchet structures **122**. It will be appreciated that other shapes and methods for making ratchet structures may be used. The purpose of ratchet bushing **126** is to receive the anchor top and secure it to the anchor base **100**. It will be appreciated that other methods of securing the anchor top to the anchor base **100** may be used, such as a frictional fit or threading. Furthermore, the anchor top may be coupled to the anchor base **100** using means other than hole **108** and bushing **126**. For example, the anchor top may be coupled via structures at the perimeter rather than the center or by a hinge.

FIG. **4**D depicts a cross section through the center of anchor base **100**. This view illustrates central bore **130** and groove **110**. The proximal surfaces **112**, **114**, **116**, **118**, and **120** are also apparent. Central bore **130** preferably does not extend all the way through the anchor base **100**. Instead, a smaller bore **132** is present at the distal end **102** of the anchor base **100**. Smaller bore **132** is used to receive a wire connected to an anchor inserter. It will be appreciated that other structures than bore **132** may be used for attaching the wire and that other means than a wire may be used to secure the anchor to the anchor inserter.

FIGS. **5**A through **5**C illustrate one embodiment of an anchor top **200**. FIG. **5**A provides a perspective view of the side and top of the anchor top **200** and FIG. **5**B provides a perspective view of the side and bottom of the anchor top **200**. Anchor top **200** has two members, a distal member **202** and a proximal member **204**. The distal member **202** comprises an elongated shaft, the longitudinal direction of which shall be considered to run along the axis of the distal member **202**. A series of grooves or other mating or locking surfaces or structures **206** exist along a portion of the outside surface of the shaft. The distal member **202** is designed to be inserted into the central bore **130** of the anchor base **100**. The ratchet structures **122** in the anchor base **100** engage grooves **206** to couple the anchor top **200** to the anchor base **100**. The ratchet structures **122** are oriented such that the distal member **202**

can be easily moved in the distal direction in central bore **130** with the ratchet structures **122** snapping into the grooves **206** as the distal member **202** is moved downward. However, when the ratchet structures **122** are snapped into grooves **206**, proximal movement of distal member **202** is inhibited. Thus, the anchor top **200** may be ratcheted down into anchor base **100**. Because the ratchet structures **122** exist along substantially the entire surface of the central bore **130** (see FIG. **4**C), the anchor top **200** may be coupled to the anchor base **100** in several positions. In other words, in one embodiment the anchor top **200** need not be ratcheted into the anchor base **100** as far as it will go for it to be secured to the anchor base **100**.

The proximal member **204** of anchor top **200** is generally cylindrical in shape with a diameter larger than distal member **202**. A hole **208** may advantageously be provided in the center of proximal member **204**. With reference to FIG. **5**B, the bottom of distal member **202** also contains a hole **210**. Holes **208** and **210** open into a central bore through the anchor top **200**. This central bore allows the wire referred to above to extend through the anchor top **200** to be secured to bore **132** in the anchor bottom **100**, thus allowing the anchor bottom **100** to be attached to an anchor inserter while still allowing anchor top **200** to be ratchet into anchor bottom **100**. FIG. **5**B also illustrates that proximal member **204** contains a groove **212** in its distal surface. Thus, the distal surface of proximal member **204** is not flat and comprises distally facing surfaces **214** and **216** and side facing surfaces **218** and **220**. In some embodiments, some or all of these surfaces may be textured such as with a scallop shape or grooves so as to inhibit movement of suture material pressed against the surfaces. In some embodiments, texturing in the distal surfaces of proximal member **204** match texturing in the proximal surfaces of anchor base **100**. It will be appreciated that the illustrated embodiments represent only one possibility; thus, other shapes for the distal surface of proximal member **204** may also be used. FIG. **5**C depicts a cross section through the center of anchor top **200**. In this figure, the central bore **226** is depicted as are surfaces **214**, **216**, **218**, and **220** and grooves **206**.

FIGS. **6**A and **6**B depict cross sections showing how the anchor top **200** may be coupled to anchor base **100** to form the complete anchor **300**. In FIG. **6**A, the anchor top **200** is coupled to anchor base **100** with the proximal member **204** separated from the anchor base **100**. The anchor top **200** is secured to anchor base **100** by distal member **202** extending into central bore **130** of the anchor base **100**. The distal member **202** is secured by ratchet structures (not shown) engaging grooves **206** in distal member **202**. Central bore **226** in anchor top **200** and central bore **130** in anchor base **100** allow a wire to extend into the top of the anchor **300** and be secured to bore **132**. Alternatively, the wire may be secured at other locations within central bore **130**. Thus the wire, which can be coupled to an anchor inserter, can hold the entire anchor assembly **300** and still allow anchor top **200** to move relative to anchor base **100** and the wire.

FIG. **6**B depicts the anchor assembly **300** with the distal member **202** of anchor top **200** ratcheted all the way into central bore **130** in anchor base **100**. In this configuration, it can be seen that proximal surfaces **112**, **114**, **116**, **118**, and **120** of the anchor base **100** and distal surfaces **214**, **216**, **218**, and **220** of the proximal member **204** of anchor top **200** form passageways **302** and **304**. The size of passageways **302** and **304** are advantageously such that when a suture passes through them, it will be compressed so that it is securely attached to the anchor **300**.

Another embodiment of the present invention is an inserter designed to insert and manipulate an anchor such as described in FIGS. **1-3**. One such inserter **400** is depicted in FIGS. **7**A and **7**B. Inserter **400** comprises a handle **402** and an outer tube **404**. As depicted in FIG. **7**A, the handle **402** comprises a cover **403**. FIG. **7**B depicts the inserter **400** with cover **403** removed. Not depicted in FIGS. **7**A and **7**B are an inner tube disposed inside outer tube **404** and a wire disposed within the inner tube. As will be described in more detail below, the inner and outer tubes may be used to manipulate an anchor **300** such as that described in FIGS. **4-6**. The wire may be used to couple the inserter **400** to the anchor **300** as described above. Inserter **400** also comprises an outer tube manipulator **406** and a wire manipulator **408**. Outer tube manipulator **406** comprises release button **410**. Outer tube manipulator **406** is securely attached to outer tube **404**. Outer tube manipulator **406** may move longitudinally relative to handle **402** and the inner tube when release button **410** is pressed. Thus, when outer tube manipulator **406** is moved, outer tube **404** also moves.

Wire manipulator **408** comprises wire grabber **410** to which the wire is attached. The wire extends from wire grabber **410**, through handle **402**, and then through the inner tube. In one embodiment, wire manipulator **408** also comprises a release button **412**. When release button **412** is pressed, the wire manipulator **408** may be pressed into the handle **402** to contact and thus provide additional tension on the wire. When in use, the additional tension causes the anchor base **100** to mover relative to inserter **400**. When enough tension is provided to the wire by wire manipulator **408**, the wire may break free from the anchor **300** at its attachment point in bore **132** or at some other predetermined location along the wire. It will be appreciated that any suitable breakable attachment means may be used for securing the wire to the anchor **300**. For example, the wire may be frictionally secured into bore **132** or it may welded to the anchor base **100** using a weld that is weaker than the wire itself or a portion of the wire where breaking is desired may be weakened. In one embodiment, the wire is notched so as to create a weaker region in the wire that will break upon application of suitable force.

The tip **414** of outer tube **404** is depicted in more detail along with inner tube **420**, wire **422**, and anchor **300** in FIG. **8**. The end of outer tube **404** may comprise a hex nut driver structure **424** for receiving the hex nut structure **106** of anchor base **100**. Of course, any other suitable engagement structure can be provided on the inserter **400** and the anchor base **100** in order to facilitate placement of the anchor base **100**. Wire **422** extends out of inner tube **420** and into the central bore in the anchor top **200** to attach to anchor base **100** as described above. In some advantageous embodiments, the wire length and tension is adjusted such that the proximal member **204** of anchor top **200** buts against the end **426** of inner tube **420**.

FIGS. **9**A through **9**E depict how inserter **400** and anchor **300** may be used to insert the anchor **300** into bone and attach a suture to it. FIG. **9**A depicts the configuration for inserting the anchor **300** into bone. Outer tube **404** and outer tube manipulator **406** (see FIGS. **7**A and **7**B) are positioned relative to inner tube **420** and handle **402** (see FIGS. **7** and **8**) so that the outer tube **404** engages hex nut structure **106** in the anchor base **100**. It is advantageous in this configuration for the anchor top **200** to be in a position relative to the anchor base **100** such as depicted in FIG. **6**A. In the configuration of FIG. **9**A, a surgeon may then screw the anchor base **100** into bone by twisting handle **402** of inserter **400** (see FIGS. **7**A and **7**B).

After the anchor base **100** is inserted into the bone, the outer tube **404** may be slid backward relative to the inner tube **420** and handle **402** to expose the anchor top **200** such as in FIG. **9**B. One or more lengths of suture **600** may then be placed in the space between the distal surface **602** of the

proximal member **204** of anchor top **200** and the proximal surface **604** of the anchor base **100** by moving the suture laterally into the space as depicted in FIG. **9**C. The suture **600** may be manually tensioned as desired. In some embodiments, tensioning of the suture **600** is aided by pulling the suture **600** against the distal member **202** of the anchor top **200**.

After appropriate tensioning of suture **600**, wire manipulator **408** may be pressed to tension the wire, causing the handle **402** of the inserter **400** and the inner tube **420** to be pulled down towards the anchor base **100** so that inner tube **420** ratchets the anchor top **200** down into the anchor bottom **100** as depicted in FIG. **9**D. As the anchor top **200** is pushed axially down, suture **600** will be clamped between the distal surface **602** of the proximal member **204** of anchor top **200** and the proximal surface **604** of the anchor base **100** (see also FIG. **9**C). The clamping will force the suture to be compressed within the passageways **302** and **304** depicted in FIG. **6**B and thus be secured to anchor **300**. The fit between the anchor top **200** and the anchor base **100** in the clamping region is such that the suture **600** is firmly gripped, but is not cut, when it is clamped in place. Appropriate edges that may contact the suture are preferably beveled or rounded to avoid damage to the suture. After anchor top **200** is ratcheted sufficiently into anchor base **100**, wire manipulator **408** (see FIGS. **7**A and **7**B) in inserter **400** may be compressed further to further tension wire **422** (see FIG. **8**) such that wire **422** breaks free from its attachment to anchor base **100**, thus leaving the anchor **300** free from inserter **400** with suture **600** securely attached as depicted in FIG. **9**E.

Although a particular inserter device for inserting and manipulating anchor **300** has been described, it should be understood that other inserter designs may be used for manipulating the parts of anchor **300** described above to insert the anchor into bone and secure suture material to the anchor. For example, it may be possible to use separate tools for inserting the anchor and securing the suture material. In addition, in alternative embodiments, the anchor base **100** may be connected to the anchor top **200** throughout the procedure, or the anchor base may be separately inserted into the bone, and the anchor top can be attached thereafter by axially sliding the distal end of the anchor top **200** into the hole **108** in the anchor base **100**.

It will be appreciated by those of skill in the art that the anchor **300** and inserter **400** provide a system for easy attachment of a suture to bone. The anchor **300** may be inserted into bone with minimal disruption of surrounding tissue. Only an access route having the diameter of the outer tube **404** and the anchor base **100** is required. Furthermore, the suture can be securely attached to the anchor **300** and tensioned as desired without having to insert additional instrumentation into the site or without performing any cumbersome attachment maneuvers such as knot tying. It should also be appreciated that the general principle illustrated by this system of inserting an anchor into bone without having suture material pre-attached and then attaching suture to the anchor without tying any knots may be implemented using any appropriate system other than the specific embodiments depicted in FIGS. **4**-**9**.

Tissue and Bone Piercing Anchor

One embodiment is a bone anchor adapted for piercing through the soft tissue and into underlying bone. In one embodiment, the suture material may be pre-attached to the piercing bone anchor so that after implantation, a suture passes from the bone anchor through to the top of the soft tissue for easy passing over the soft tissue. In one embodiment, the piercing bone anchor has two configurations, a first configuration having a small diameter for easy piercing through soft tissue and bone and a second deployed configuration where structures such as protrusions are deployed to prevent the bone anchor from being easily removed from the bone.

In one embodiment, the anchor includes a substantially hollow cylinder having a portion of its walls cut in such a manner so as to allow the cylinder to deform under axial stress and form lateral protrusions. The lateral protrusions may thus prevent the anchor from being easily removed from the bone after deployment. In one embodiment, the anchor comprises a pointed tip coupled to the hollow cylinder for piercing the soft tissue and bone. In one embodiment, suture is pre-attached to the pointed tip inside of the hollow cylinder. In other embodiments, suture is pre-attached at other locations on the piercing anchor, such as at the proximal end of the hollow cylinder.

One embodiment of a deployable piercing anchor is depicted in FIGS. **10**A and **10**B. In FIG. **10**A, the anchor is depicted in a pre-deployed state. The anchor includes a substantially hollow cylinder **650** with a plurality of cuts **652** in the side of the cylinder **650**. The cylinder **650** is open on one end **654**. On the other end, a pointed tip **656** is disposed, allowing the anchor to pierce through soft tissue and bone. In FIG. **10**B, the anchor is depicted in a deployed state. Stress is applied in an axial direction such that the cylinder **650** collapses along cuts **652** so as to form two lateral wings **660**. The lateral wings **660** prevent the anchor from being removed from the bone. Hinges **662** connect one end of each wing to either the top or the bottom parts of anchor body. These hinges deform and fold, in the plane tangent to the anchor body at that point when the anchor is deployed. A strip of material **664** connects the top and bottom wing on each side of the anchor body, and serves as a hinge between the two as well as aiding in alignment of the wings during deformation. The tips of the wings adjacent to the connecting strip **664** utilize rolling edges **666**, which ensure uniform alignment and smooth transition during deformation. Those of skill in the art will appreciate that any number of geometries of cuts in the cylinder **650** may be utilized to create a deformable structure that will produce lateral protrusions upon exposure to stress.

In some embodiments, structures may be positioned within the cylinder **650** for attaching sutures and engaging with an anchor inserter. In one embodiment, such structures are coupled to the anchor tip **656** within the cylinder **650**. FIG. **11** depicts one such embodiment. Attached to the tip **656** is a structure **670** through which there is an aperture **672**. The structure **670** may be adapted to engage the inner surface of cylinder **650** for attaching the tip **656** to the cylinder **650**. The attachment mechanism may be by forced fit, frictional fit, threads, welding, adhesive, or any other suitable means. Suture material may be threaded through the aperture **672** in order to attach the suture to the anchor. The suture material may be secured to the tip **656** by tying the suture around structure **670**, tying a knot in the end of the suture that prevents it from being pulled through the aperture **672**, clamping the suture between the structure **670** and the inside of the cylinder **650**, adhering the suture to structure **670** by welding or adhesive, or any other suitable means. In one embodiment, the suture material is attached to the anchor at tip **656** prior to use of the anchor.

An anchor inserter attachment structure **674** may also be coupled to the tip **656**. This structure **674** may couple to an anchor inserter through a wire or any other suitable means. The attachment between the anchor inserter and the anchor at this point may be used to apply axial stress to the anchor for

deploying the anchor as described above. The attachment at this point may also serve to keep the anchor attached to the inserter prior to deployment.

One embodiment of an anchor inserter suitable for use with the above-described anchor is depicted in FIG. **12**. The anchor inserter comprises a grasping handle **700** to which is attached an outer sleeve **702** which is fixed relative to the handle **700**. The piercing anchor **704** is disposed at the end of the sleeve **702**. A deployment lever **706** may be pressed by a user to deploy and detach the anchor **704** as described below. A safety switch **708** may be provided to prevent the anchor **704** from being deployed prematurely. A spool **710** may be provided at the proximal end of the handle **700** for holding excess suture. A lid **712** may be provided for gaining access to the inner components of the inserter.

FIG. **13** depicts the anchor **704** coupled to the inserter. As described above, the anchor **704** comprises a hollow cylinder **650** with cuts in the sides and a pointed tip **656**. Furthermore, as depicted in FIG. **11**, a suture receiving aperture **672** and an inserter attachment structure **674** are attached to the pointed tip **656** within the cylinder **650**. The outer sleeve **702** of the inserter may fit over the open end **654** of the cylinder **650** or be flush with the open end **654**. The outer sleeve **702** may thus hold the top part of the anchor **704** steady during insertion. In an alternative embodiment, the outer sleeve **702** may fit over the length of the cylinder **650** to prevent the cylinder **650** from deforming while it is being inserted into bone. In this alternative embodiment, the outer sleeve **702** may be retracted prior to deployment of the anchor. An inner tube **720** may be positioned within the outer sleeve **702** and the hollow cylinder **650** and contact the top surface of the anchor tip **656** (see FIG. **11**). The inner tube **720** provides structural reinforcement of the anchor **704** and pushes against the tip of the anchor **704** while it is being driven into bone or tissue. The inner tube **720** may be fixed relative to the handle **712** and outer sleeve **702** during insertion, however, during deployment of the anchor **704**, the inner tube **720** may be released by switching safety switch **708** so that the inner tube **720** can move axially relative to the outer sleeve **702** while the anchor cylinder **650** collapses. A wire may be positioned inside of the inner tube **720** running from within the handle **712** through the inner tube **720** to the anchor **704** and attached to the anchor inserter attachment structure **674**. During deployment, the lever **704** may be pressed to pull the wire axially towards the handle **700**. The axially movement of the wire forces the anchor **704** to press against outer sleeve **702** and stresses the cylinder **650**, causing it to deform and deploy. During collapse of the cylinder **650**, the inner tube **720** will also move in an axial direction toward the handle **700**. Upon further stress on the wire, the wire may break free from the anchor inserter attachment structure **674**, releasing the inserter from the anchor **704**. Suture material may run from the inside of handle **700** through the inner tube **720** to attach to the anchor **704** through aperture **672** (see FIG. **11**). Upon detachment of the anchor inserter from the anchor **704**, the inserter may be withdrawn, leaving the inserted and deployed anchor with suture coming out of the open end **654** of the cylinder **650**. The suture will still be coupled to the inserter through the inner tube **720**, handle **700**, and around spool **710**. Those of skill in the art will appreciate other inserters and mechanisms that may be used to insert and deploy the piercing anchors described herein. For example, rather then axially stressing the anchor **704** by pulling the tip **656** in an proximal direction, the cylinder **650** may be pushed in a distal direction to deform the cylinder **650**.

FIG. **14** is a cut-away view of the handle **700**, showing the inner workings of the anchor inserter. The suture material attached to a piercing anchor at the tip of the inserter may pass through the central bore of the inner tube **720** and through a bore **750** in the handle **700**. The suture material may then pass through a hole **752** in the end of the handle **700** and be wrapped around the spool **710**, which may be integral with the handle **700**. The wire attached to the anchor inserter attachment structure **674** in the anchor may also pass through the central bore of the inner tube **720** and may then proceed around a pulley **754** and attach securely to the handle **700** at point **756**. The pulley **754** may be attached to the lever **706**. When the lever **706** is pressed down, the pulley **754** will move toward the back end of the handle **700**, causing the wire attached to the anchor to retract. Because of the use of pulley **754**, the wire will retract twice the distance as the pulley **754** moves.

The safety switch **708** may be used to prevent the lever **706** from being pressed and prevent the inner tube **720** from moving unless the safety switch **708** is in the correct position. The safety mechanism operates via a drum **760** disposed within the handle **700** to which the safety switch **708** is attached. Moving the safety switch **708** rotates the drum **760** within the handle **700**. FIG. **15** shows the drum **760** and safety switch **708** mechanism in more detail. The inner tube **720** passes through a central bore in the drum **760**. On the other side of the drum **760**, the inner tube **720** is attached to a stopper **762**. The stopper **762** has a through-hole **764** to permit passage of the deployment wire and suture. The stopper **762** may be positioned within a cavity **766** in the end of the drum **760**. A second similarly shaped cavity may be disposed within the handle **700**. The stopper **762** and attached inner tube **720** may only be allowed to move axially relative to the handle **700** when the safety switch **708** and drum **760** is rotated so that the cavity **766** in the drum **760** is aligned with the matching cavity in the handle **700**. When the cavities are aligned, the stopper **762** is allowed to move from the cavity **766** to the cavity in the handle **700**, thus allowing the inner tube **720** to move axially and the anchor to be deployed.

Additionally, the drum **760** comprises a groove **768**. A spring-loaded sliding pin **770** (see FIG. **14**) may be coupled to the lever **706**. The lever **706** can only be moved when the drum **760** and switch **708** are rotated so that groove **768** is aligned with the pin **770**. Thus, both the stopper **764** and the pin **770** prevent the anchor from being deployed unless the switch **708** is in the correct position.

Those of skill in the art will appreciate other mechanisms that could be used for deploying a deployable anchor and providing safety mechanisms to prevent premature deployment.

Example Using a Piercing Anchor and a Suture Capturing Anchor

The above-described anchors may be used in a surgical procedure for attaching soft tissue to bone. One example of such a procedure is depicted in FIGS. **16**A through **16**F. In FIG. **16**A, the piercing anchor **800** attached to an anchor inserter **802** as described above is pierced through soft tissue **804** that has become detached from underlying bone **806**. In FIG. **16**B, the anchor inserter **802** is moved laterally relative to the bone **806** so as to stretch the soft tissue **804** laterally relative to the bone **806**. Once the soft tissue **804** has been stretched to the desired position, the anchor **800** is inserted into the bone **806** and the anchor **800** is deployed as described above and the inserter **802** is detached from the anchor **800**, leaving a suture **808** attached to the anchor **800** and extending through the soft tissue **804**. The anchor **800** may be inserted into bone **806** by tapping on the inserter **802** with a hammer or by any other suitable means of applying axial force. FIG. **16**C

depicts the deployed anchor **800** with attached suture **808**. The suture **808** will extend into the inserter **802**.

Next, as depicted in FIG. **16**D, a suture capturing anchor **810** is inserted into the bone **806** using the inserter **812** as described above. In FIG. **16**E, the inserter **812** is then retracted to expose the suture capturing mechanism. The suture **808** is then passed over the soft tissue **804** and laterally moved into the suture capturing mechanism and tensioned. Finally, as depicted in FIG. **16**F, the suture capturing mechanism is deployed to capture the suture **808**, the anchor inserter **812** is detached from the anchor **810**, and the suture **808** is cut to detach it from the suture inserter **802**. The result is a length of suture **808** between the bone anchors **808** and **810** that presses the soft tissue **804** against the bone **806**. Multiple anchors and sutures may be used to produce geometries such as depicted in FIGS. **2** and **3** and variations thereof.

It will be appreciated that there are numerous stitches, suture threading patterns, and anchor patterns that may be used to secure soft tissue to bone by the methods and devices described herein. These variations as well as variations in the design of the above described anchor devices and inserter devices are within the scope of the present disclosure.

Methods of Attaching Soft Tissue to Bone

Various embodiments include methods for attaching soft tissue to bone. In some embodiments, the methods include using the bone anchors described above. In one embodiment, a bone anchor is inserted into the bone and then a length of suture is passed over the soft tissue and secured to the anchor after inserting the anchor without tying any knots or without passing the suture through an aperture in the anchor. In some embodiments, the suture is secured to the anchor by laterally moving it into a securing mechanism. In one embodiment, securing the suture to the anchor includes clamping the suture between at least two surfaces on the anchor. In one embodiment, the anchor is not inserted further into the bone after securing the suture to it.

In another embodiment, a first anchor with a suture pre-attached is inserted through the soft tissue and into the bone. The suture may then be passed over the soft tissue and fixedly secured to a second bone anchor. In one embodiment, the first anchor is inserted by directly piercing the soft tissue and the bone. In one embodiment, lateral protrusion may be deployed on the first anchor to prevent the first anchor from being removed. In one embodiment, the suture may be coupled to the second bone anchor prior to insertion and then fixedly secured after insertion. In this context, "coupled" means that the suture is attached to the bone anchor but not fixedly secured, such that the suture can move to some extent relative to the bone anchor. In an alternative embodiment, the suture is not coupled to the second bone anchor during its insertion.

In another embodiment, a first portion of suture is inserted into the proximal surface of the soft tissue. A second portion of the suture (e.g., the portion proximal to the inserted portion) is then passed over the proximal surface of the soft tissue and fixedly secured to a bone anchor. In one embodiment, the procedure may be performed without passing the first portion of the suture back out of the proximal surface of the soft tissue. In one embodiment, this result is accomplished by the first portion of the suture being attached to an anchor that is inserted through the soft tissue and into bone.

One embodiment includes inserting a first anchor with a pre-coupled suture through soft tissue and into bone. The suture may then be passed over the soft tissue and fixedly secured to a second anchor. In one embodiment, the pre-coupled suture is fixedly secured to the first anchor prior to insertion. In an alternative embodiment, the pre-coupled suture can move relative to the first anchor prior to insertion and is fixedly secured after insertion.

In another embodiment, multiple lengths of suture are attached to multiple anchors. In one embodiment at least three anchors are inserted into bone. A first length of suture may be secured between a first and second anchor and a second length of suture may be secured between the first and a third anchor. In one embodiment, the first anchor is positioned beneath the soft tissue and the second and third anchors are positioned laterally to the soft tissue. In an alternative embodiment, the first anchor is positioned laterally to the soft tissue and the second and third anchors are positioned beneath the soft tissue. In some embodiments, the lengths of suture are fixedly secured to the anchor(s) positioned beneath the soft tissue prior to insertion of those anchor(s). In one embodiment, the different lengths of suture may be tensioned separately.

In various embodiments, prior to fixedly securing suture to a bone anchor, it can be tensioned. In one embodiment, tensioning is accomplished by manually pulling on the suture such as by a surgeon grasping the suture using an appropriate instrument and then pulling. In one embodiment, the suture may be pressed against the bone anchor to provide leverage for pulling. For example, the suture may be wrapped partly around a proximal portion of the anchor prior to pulling.

Although the invention has been described with reference to embodiments and examples, it should be understood that numerous and various modifications can be made without departing from the spirit of the invention. Accordingly, the invention is limited only by the following claims.

What is claimed is:

1. A method of attaching soft tissue to bone, comprising:
- inserting a first anchor into bone, wherein the first anchor is positioned underneath the soft tissue such that no part of the anchor extends beyond an edge of the soft tissue;
- passing a first length of suture from said first anchor over the soft tissue;
- inserting a second anchor into bone, wherein the second anchor is positioned beyond the edge of the soft tissue such that it is not underneath the soft tissue;
- after inserting the second anchor, tensioning the first length of suture to compress an area of tissue to bone between the edge of the soft tissue and the first anchor; and
- fixedly securing the first length of suture to the second anchor without tying any knots.

2. The method of claim **1**, wherein the first length of suture is fixedly secured to the first anchor prior to insertion of the first anchor.

3. The method of claim **1**, wherein the first anchor is inserted through the soft tissue.

4. The method of claim **1**, wherein the first length of suture is fixedly secured to the second anchor without passing the first length of suture through any aperture in the second anchor.

5. The method of claim **1**, comprising inserting a third anchor into bone, wherein the third anchor is positioned beyond an edge of the soft tissue such that it is not underneath the soft tissue.

6. The method of claim **5**, comprising passing a second length of suture from said first anchor over the soft tissue.

7. The method of claim **6**, comprising fixedly securing the second length of suture to the third anchor without tying any knots.

8. The method of claim **1**, wherein the first length of suture is coupled to the first anchor prior to insertion of the first anchor.

9. The method of claim 8, wherein the first length of suture is fixedly secured to the first anchor after insertion of the first anchor.

10. The method of claim 1, wherein the first length of suture is coupled to the second anchor prior to insertion of the first anchor.

11. The method of claim 1, comprising inserting a third anchor into bone, wherein the third anchor is positioned underneath the soft tissue at a location distinct from the first anchor.

12. The method of claim 11, comprising passing a second length of suture from said third anchor over the soft tissue.

13. The method of claim 12, wherein the second length of suture is crossed over the first length of suture.

14. The method of claim 12, comprising fixedly securing the second length of suture to the second anchor without tying any knots.

15. The method of claim 14, comprising inserting a fourth anchor into bone, wherein the fourth anchor is positioned beyond an edge of the soft tissue such that it is not underneath the soft tissue at a location distinct from the second anchor.

16. The method of claim 15, comprising passing a third length of suture from said third anchor over the soft tissue and the first length of suture.

17. The method of claim 16, comprising fixedly securing the third length of suture to the fourth anchor.

18. The method of claim 17, comprising passing a fourth length of suture from said first anchor over the soft issue.

19. The method of claim 18, comprising fixedly securing the fourth length of suture to the fourth anchor.

20. The method of claim 1, comprising:

inserting a third anchor into bone, wherein the third anchor is positioned underneath the soft tissue at a location distinct from the first anchor;

inserting a fourth anchor into bone, wherein the fourth anchor is positioned beyond an edge of the soft tissue such that it is not underneath the soft tissue at a location distinct from the second anchor;

passing a second length of suture from said third anchor over the soft tissue and the first length of suture; and

fixedly securing the second length of suture to said fourth anchor.

21. The method of claim 1, wherein inserting the first anchor into the bone comprises directly piercing the bone with the first anchor without drilling any holes.

22. The method of claim 1, wherein inserting the first anchor into the bone comprises deploying lateral protrusions on the first anchor, wherein the lateral protrusions are adapted to prevent the first anchor from being removed.

23. The method of claim 1, wherein the passing step comprises passing the length of suture over the soft tissue without the suture being coupled to the second anchor.

24. The method of claim 1, wherein suture is coupled to the second anchor prior to insertion and wherein, after inserting the second anchor, the length of suture is tensioned and then fixedly secured to the second anchor.

25. The method of claim 1, wherein the step of inserting the second anchor comprises inserting the anchor directly into the bone without the anchor passing through the soft tissue.

26. The method of claim 1, wherein no suture is coupled to the second anchor during its insertion and wherein, after inserting the second anchor, the length of suture is tensioned and then fixedly secured to the second anchor.

27. The method of claim 1, wherein the step of fixedly securing is performed without passing the suture through any apertures in the second anchor.

28. The method of claim 1, wherein the inserting steps, passing step, and fixedly securing step are conducted arthroscopically.

29. The method of claim 1, wherein passing the first length of suture over the soft tissue comprises passing the first length of suture over the edge of the soft tissue.

30. The method of claim 1, wherein the first length of suture passes though the soft tissue only once.

* * * * *

EXHIBIT 2

US008100942B1

(12) **United States Patent**
Green et al.

(10) **Patent No.: US 8,100,942 B1**
(45) **Date of Patent: *Jan. 24, 2012**

(54) **SYSTEM AND METHOD FOR ATTACHING SOFT TISSUE TO BONE**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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(60) Continuation of application No. 12/549,105, filed on Aug. 27, 2009, which is a division of application No. 11/143,007, filed on Jun. 1, 2005, now Pat. No. 7,585,311.

(60) Provisional application No. 60/576,477, filed on Jun. 2, 2004, provisional application No. 60/610,924, filed on Sep. 17, 2004, provisional application No. 60/634,174, filed on Dec. 7, 2004.

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A61B 17/04 (2006.01)

(52) **U.S. Cl.** **606/232**; 606/300

(58) **Field of Classification Search** 606/72, 606/75, 78, 219, 224, 232, 300–331
See application file for complete search history.

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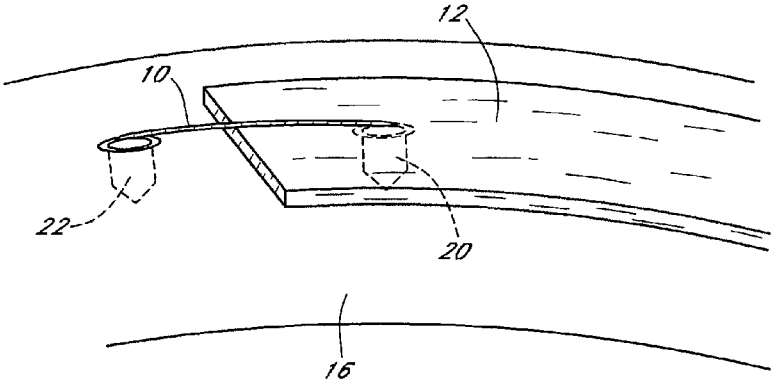
(57) **ABSTRACT**

Disclosed herein are methods and devices for securing soft tissue to a rigid material such as bone. A bone anchor is described that comprises a base and a top such that suture material may be compressed between surfaces on the base and top to secure the suture to the anchor. Also described is an inserter that can be used to insert the bone anchor into bone and move the anchor top relative to the anchor base to clamp suture material there between. Also described is a soft-tissue and bone piercing anchor and associated inserter. Methods are described that allow use of the bone anchors to provide multiple lengths of suture material to compress a large area of soft tissue against bone.

19 Claims, 24 Drawing Sheets



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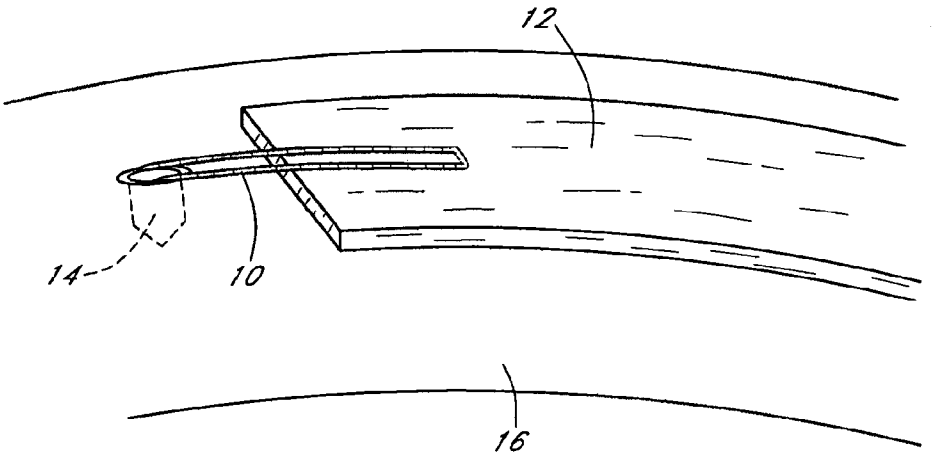

FIG. 1

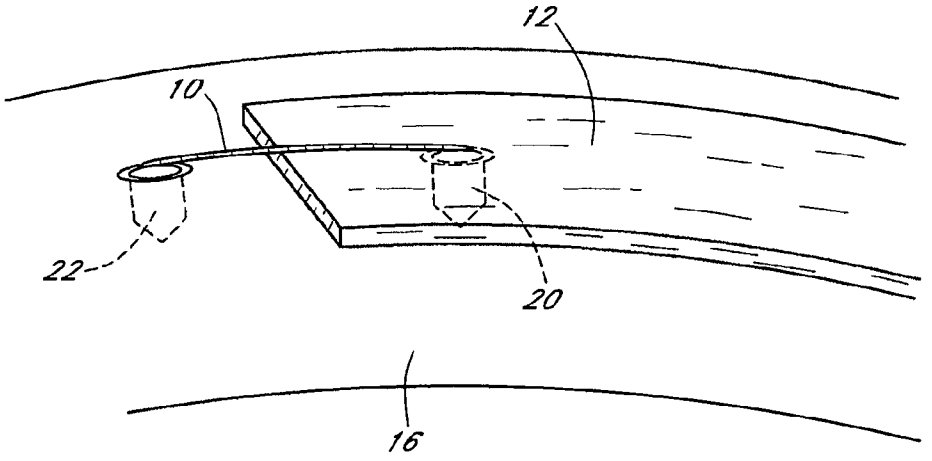

FIG. 2

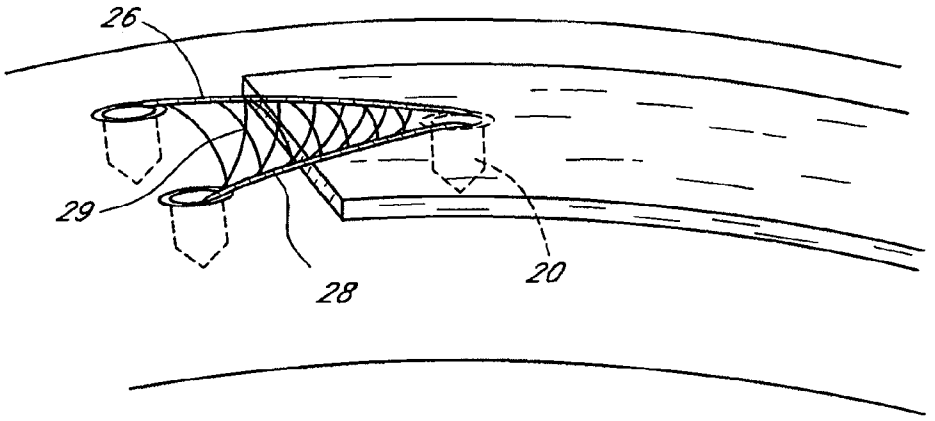

FIG. 3A

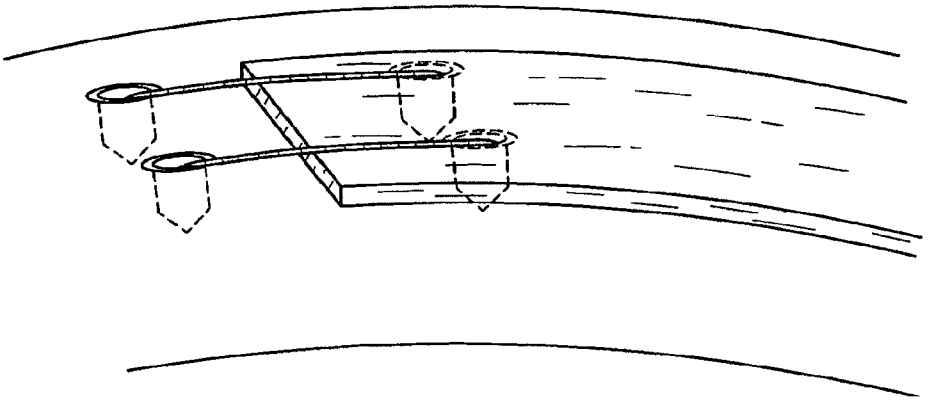

FIG. 3B

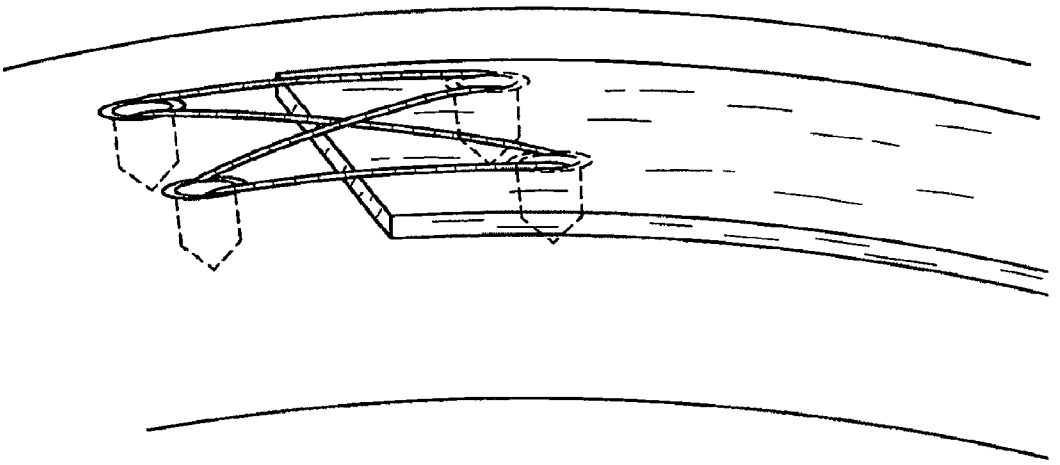

FIG. 3C

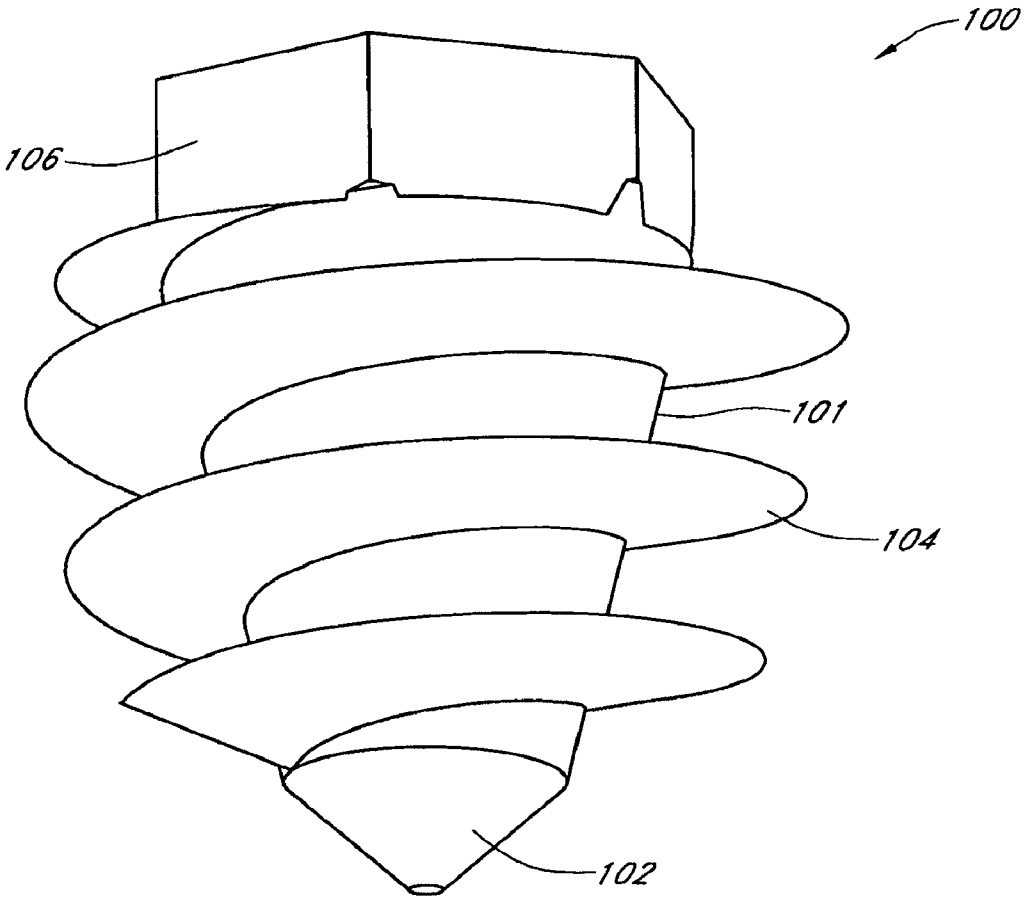

FIG. 4A

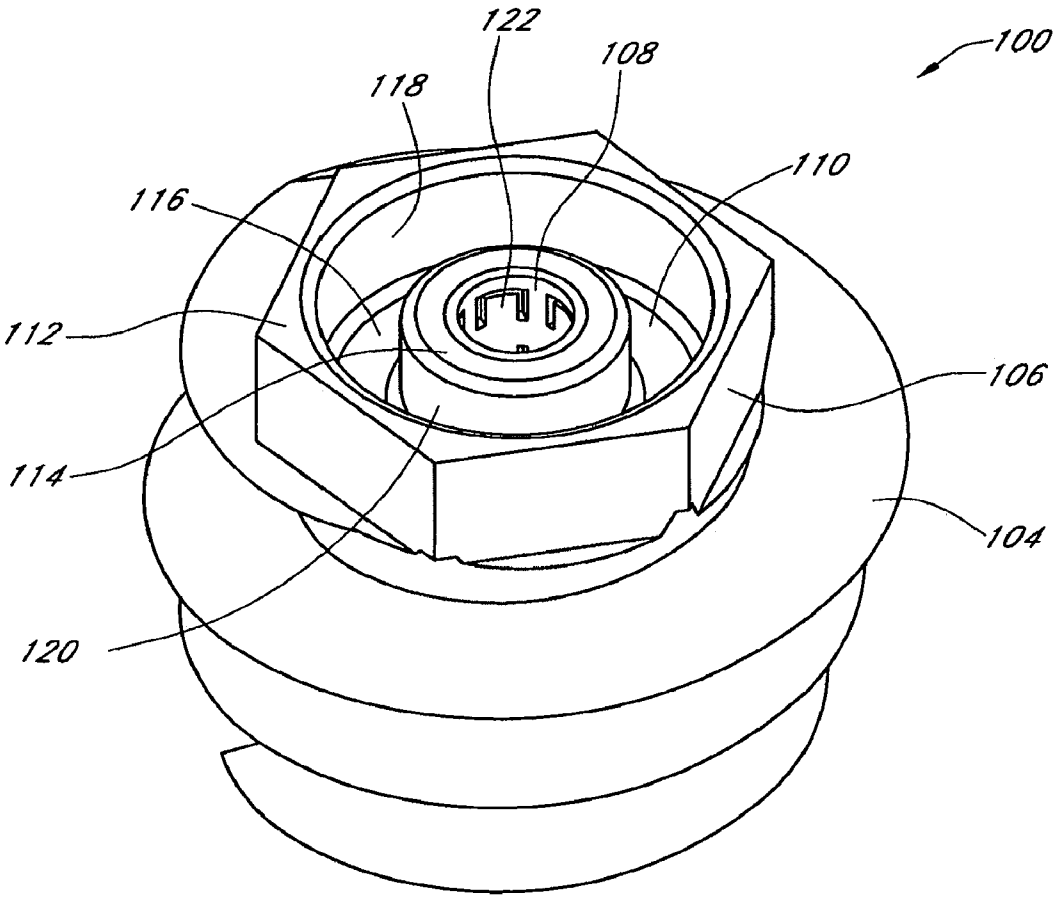

FIG. 4B

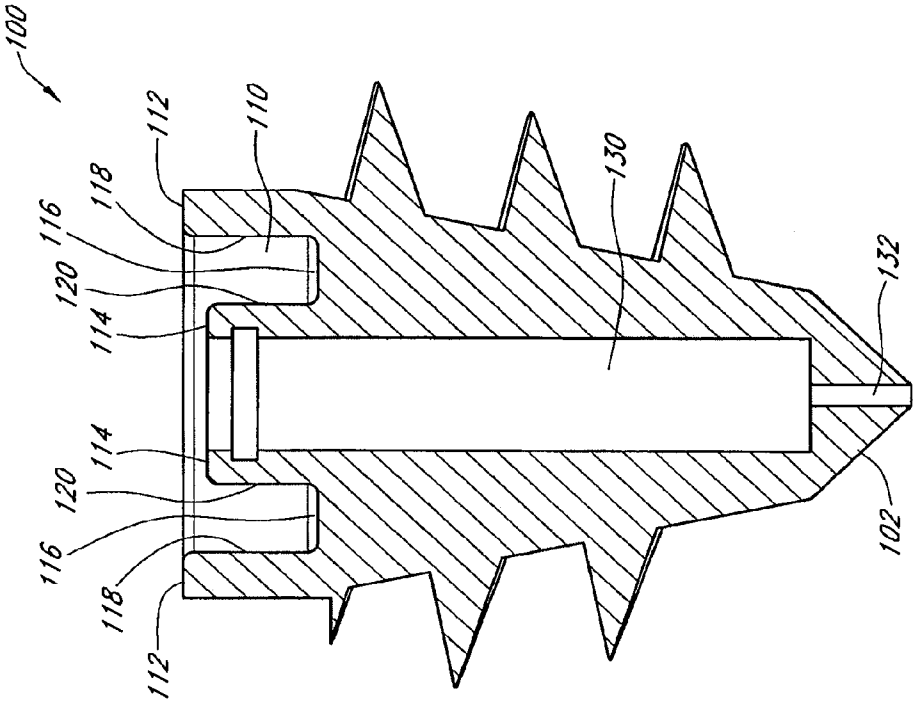
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FIG. 4D

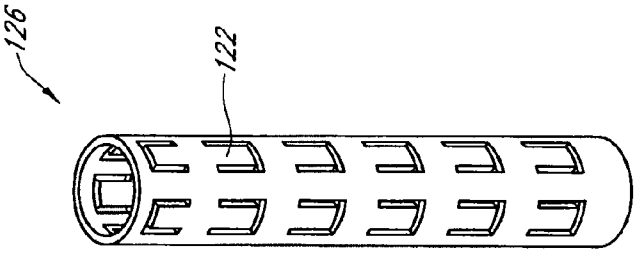
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FIG. 4C

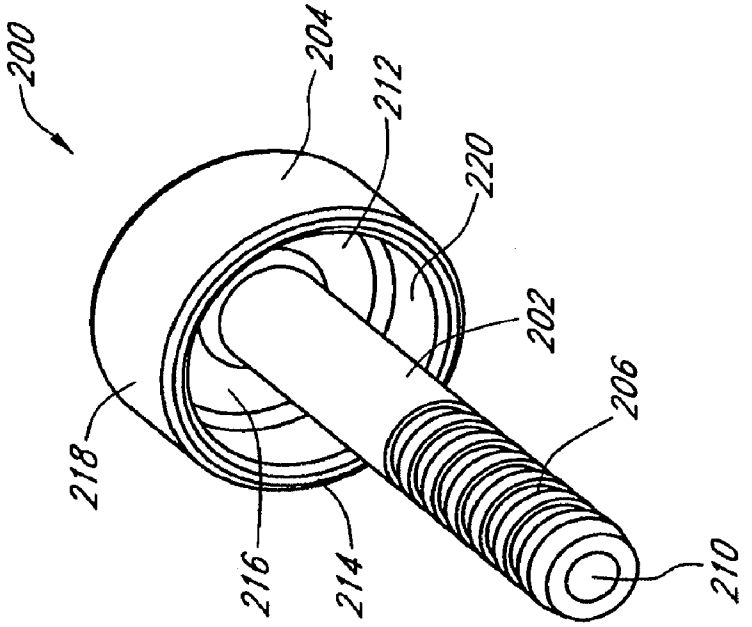

FIG. 5B

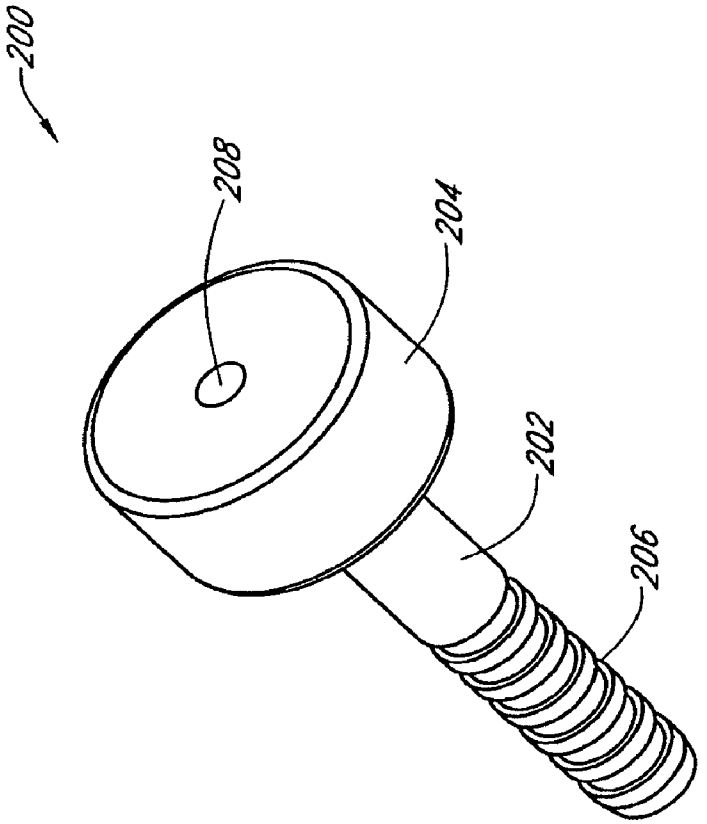

FIG. 5A

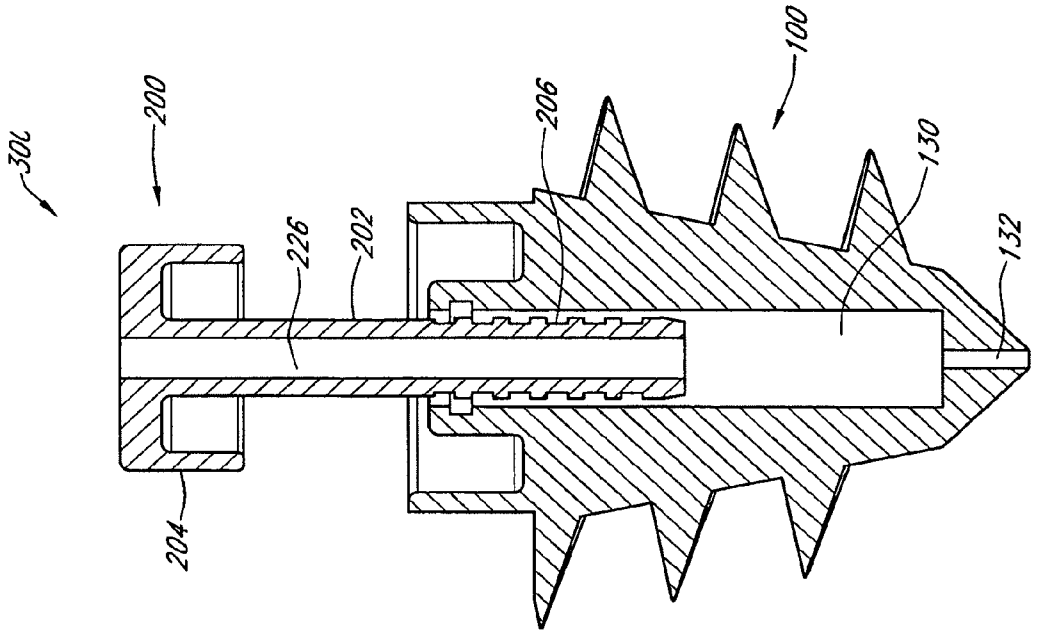
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FIG. 6A

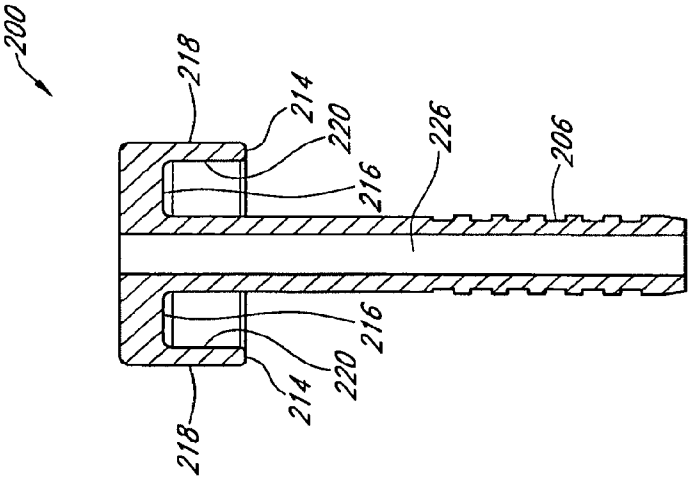
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FIG. 5C

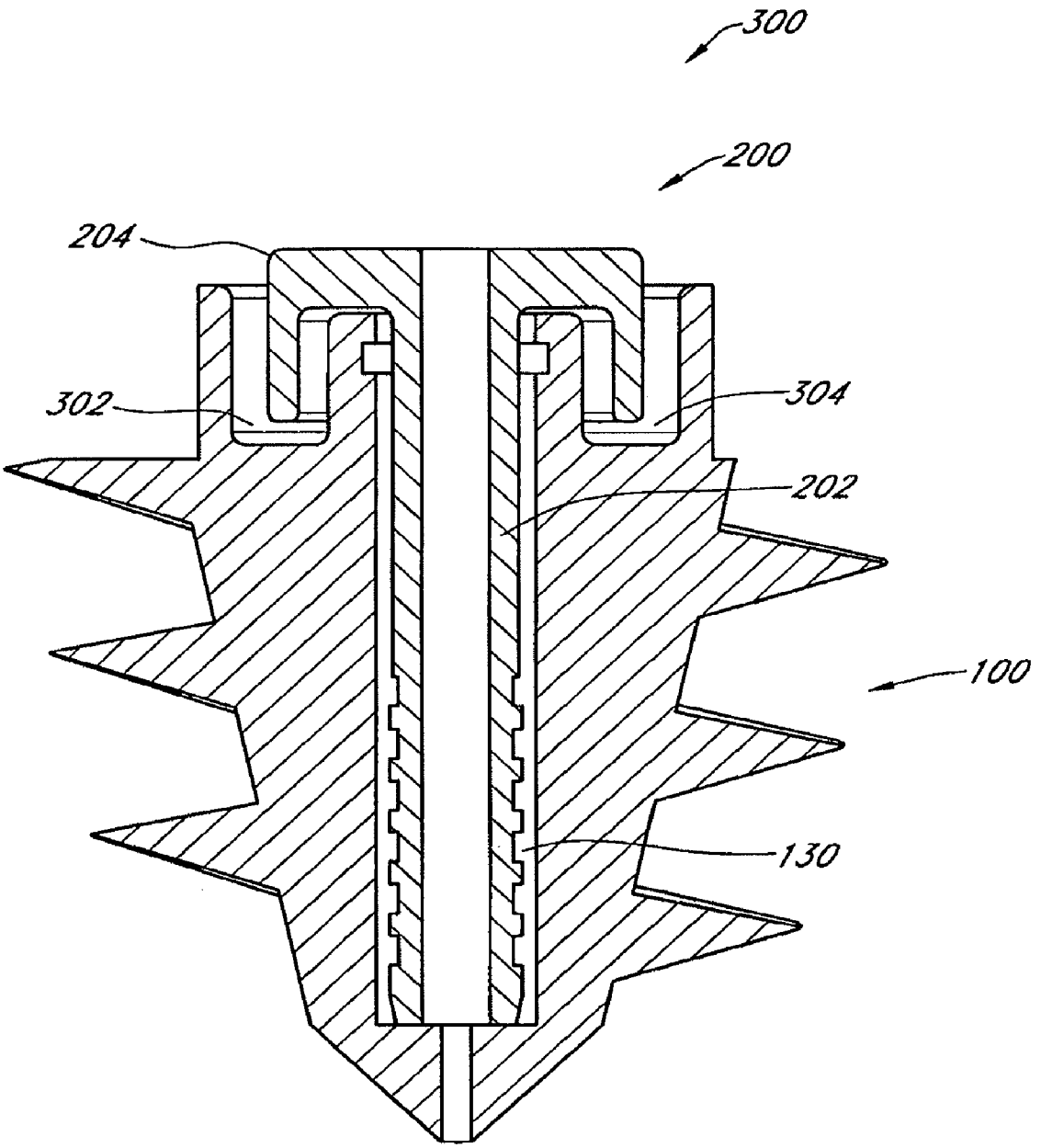

FIG. 6B

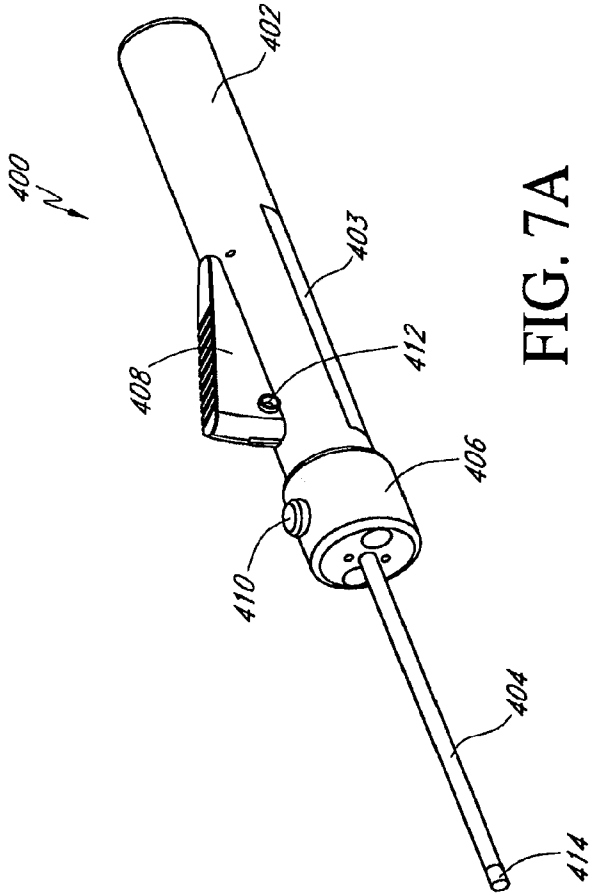
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FIG. 7A

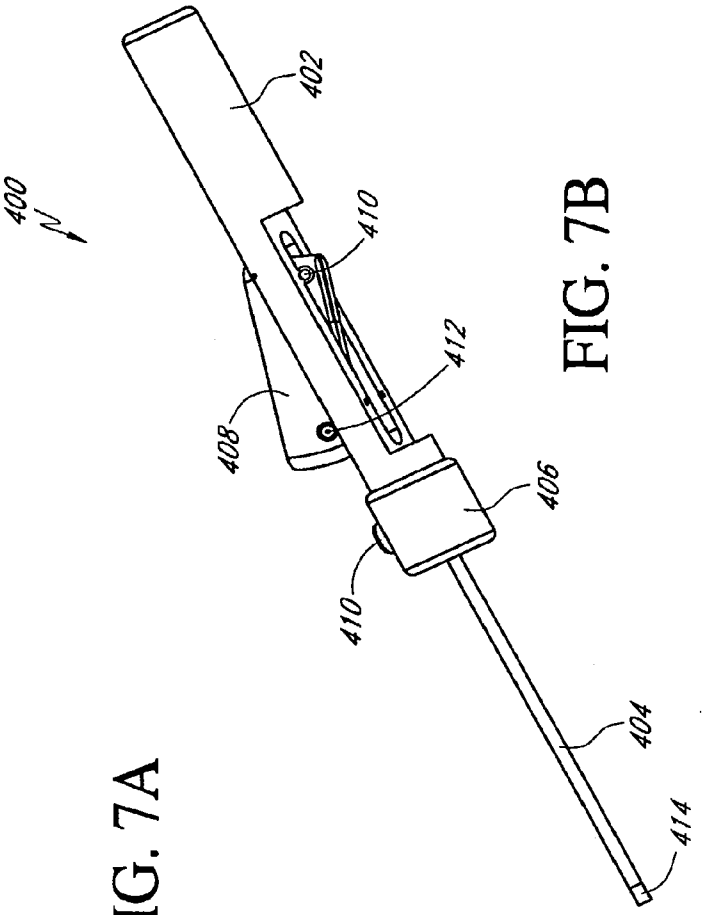
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FIG. 7B

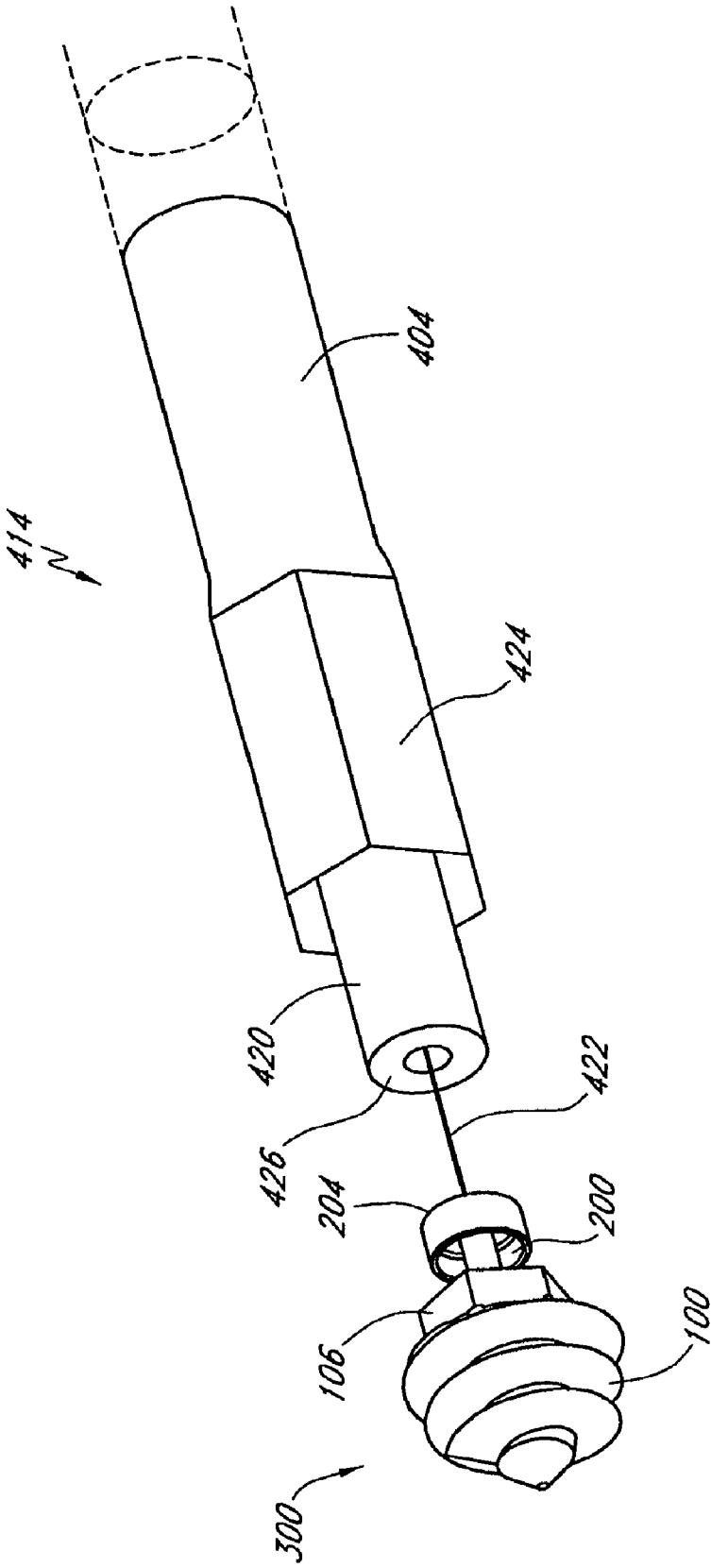

FIG. 8

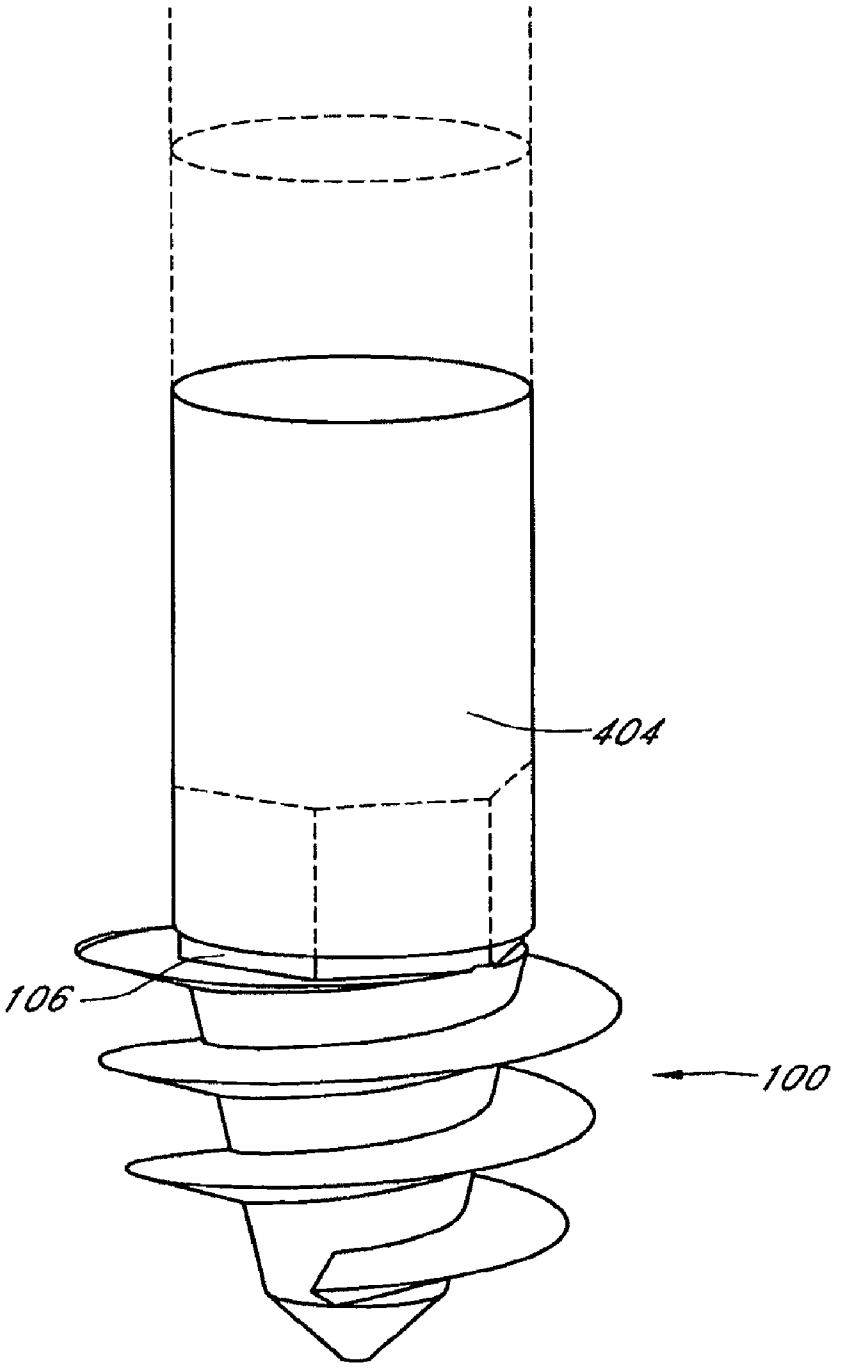

FIG. 9A

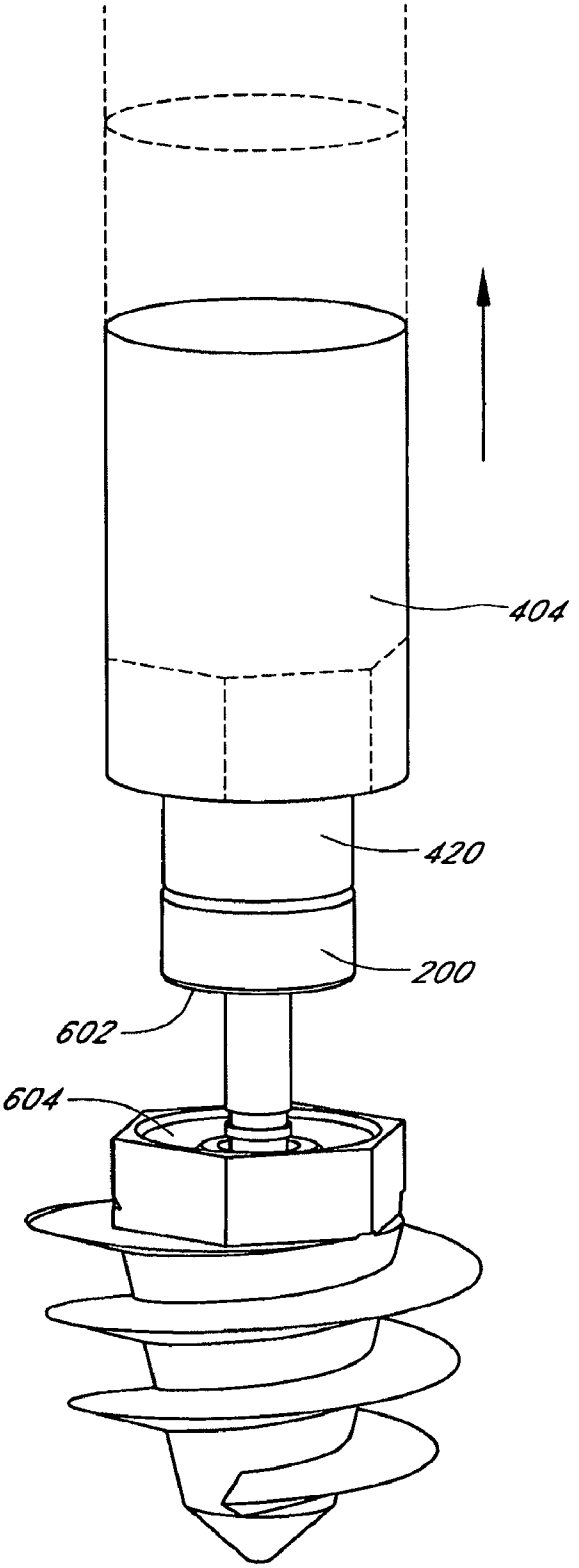

FIG. 9B

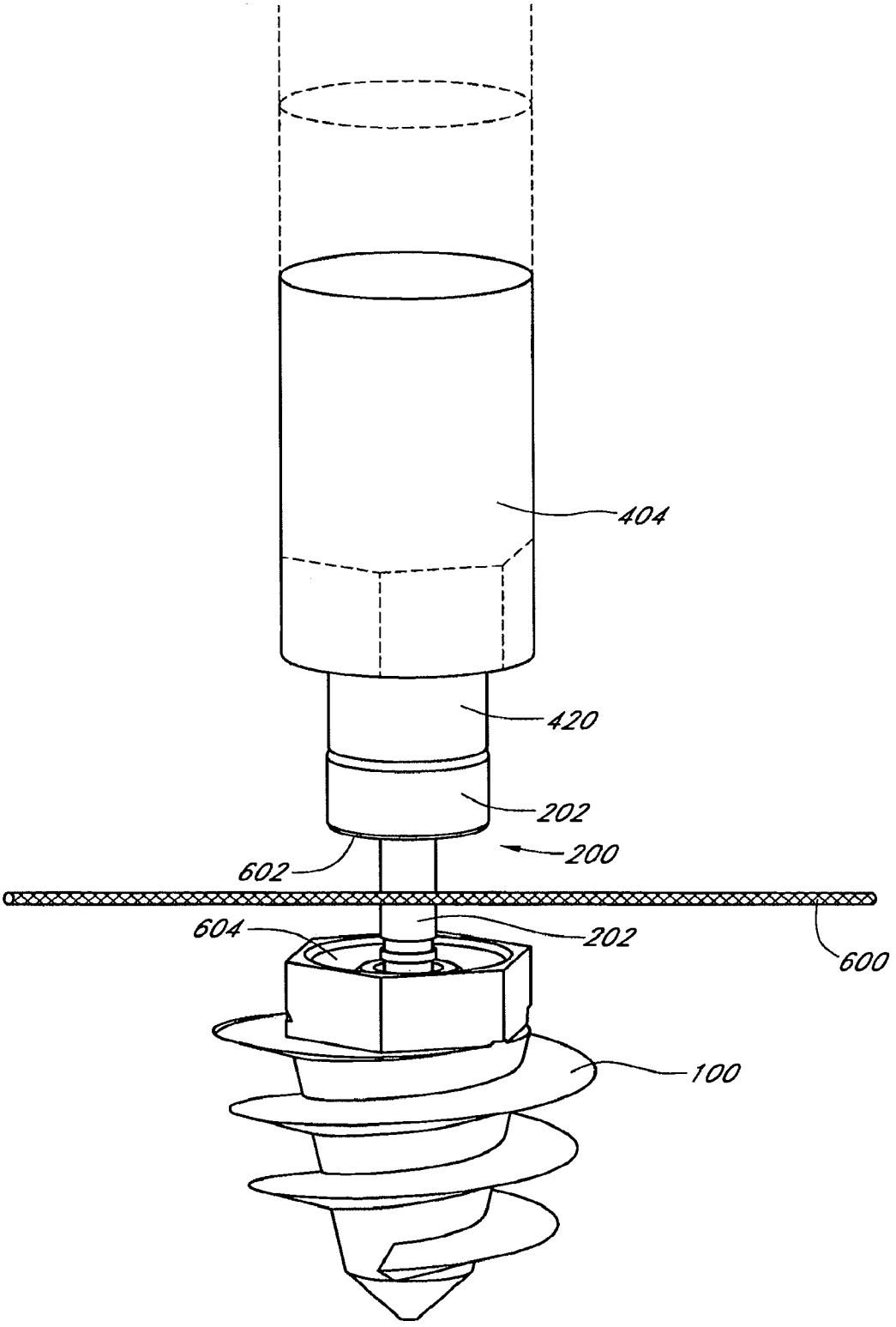

FIG. 9C

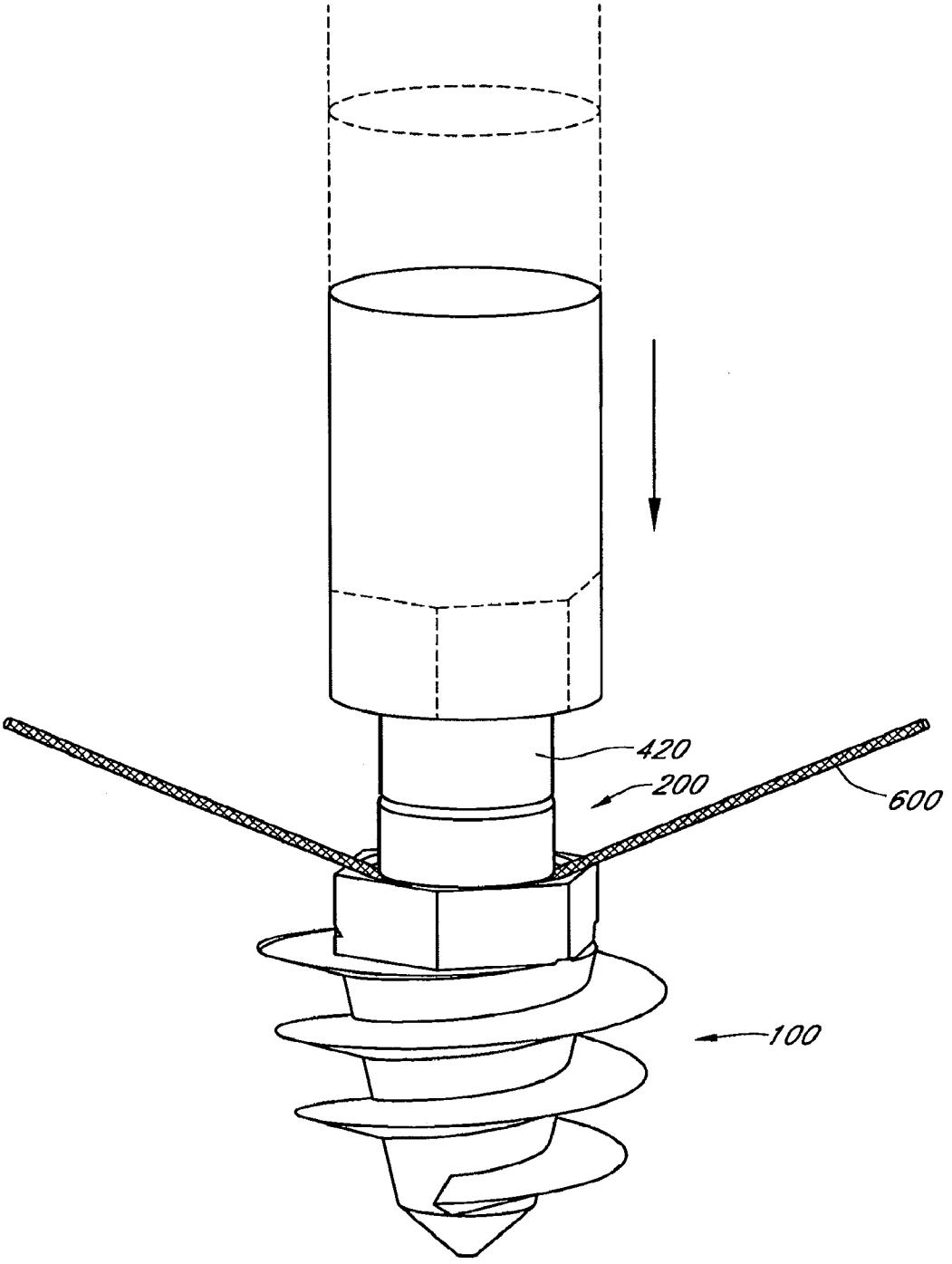

FIG. 9D

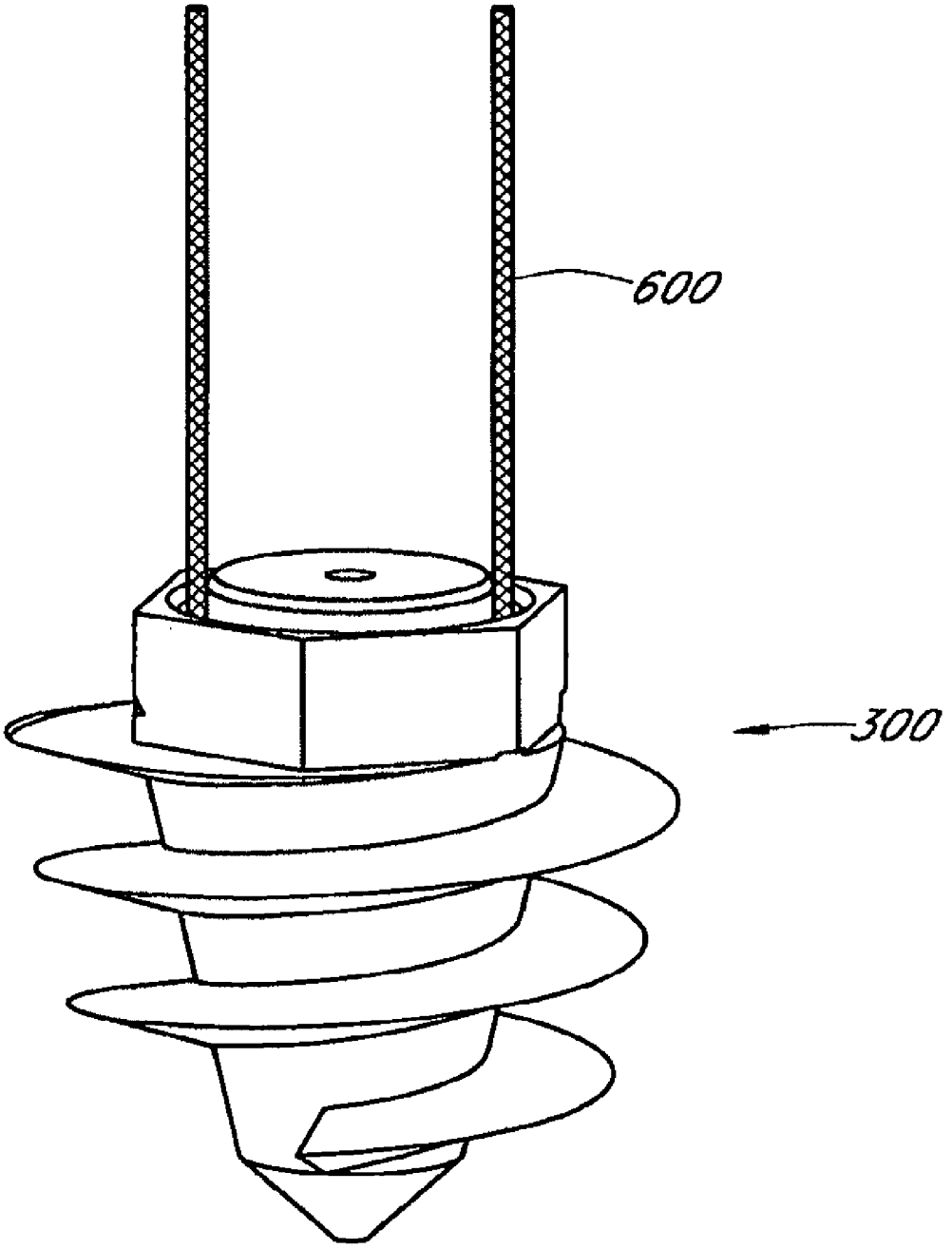

FIG. 9E

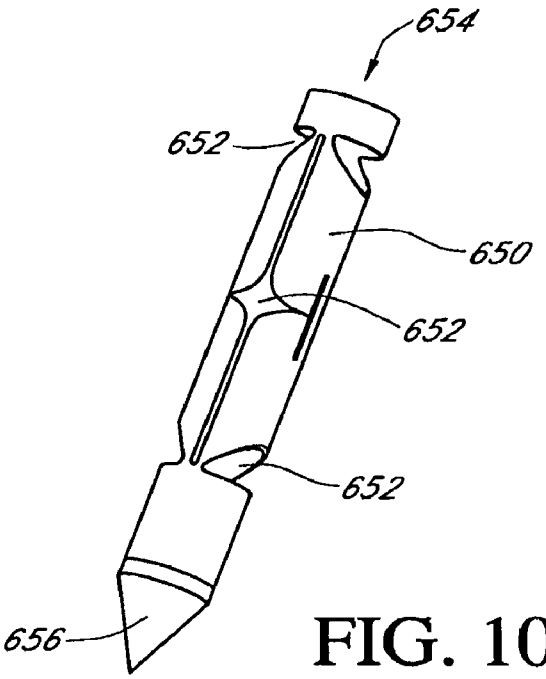

FIG. 10A

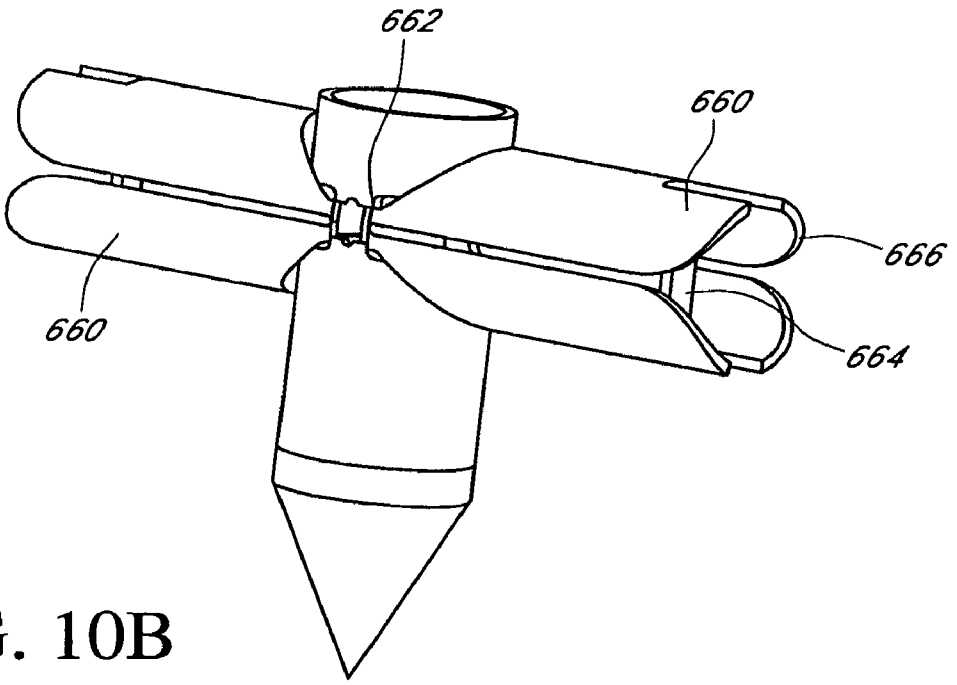

FIG. 10B

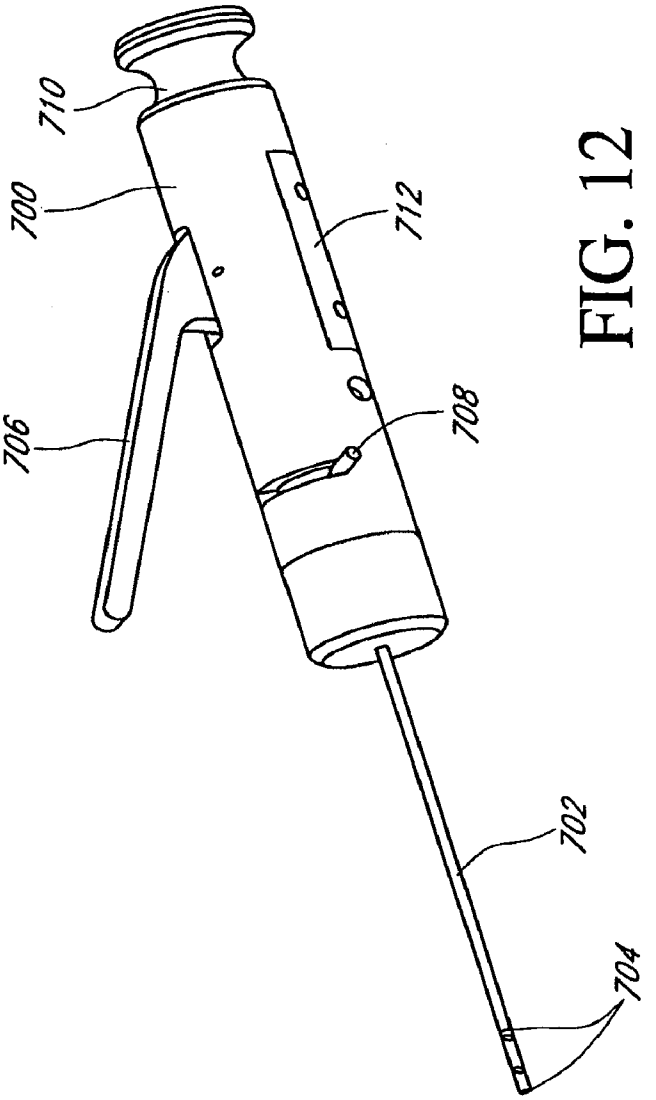

FIG. 12

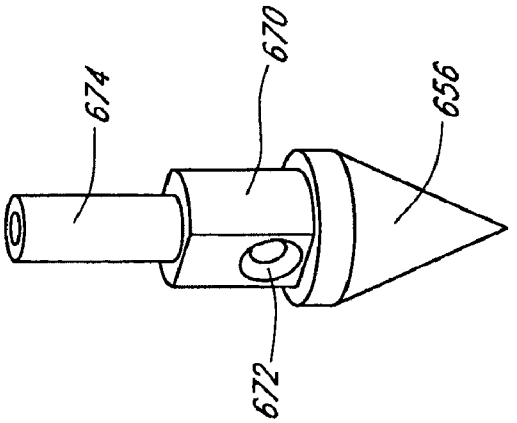

FIG. 11

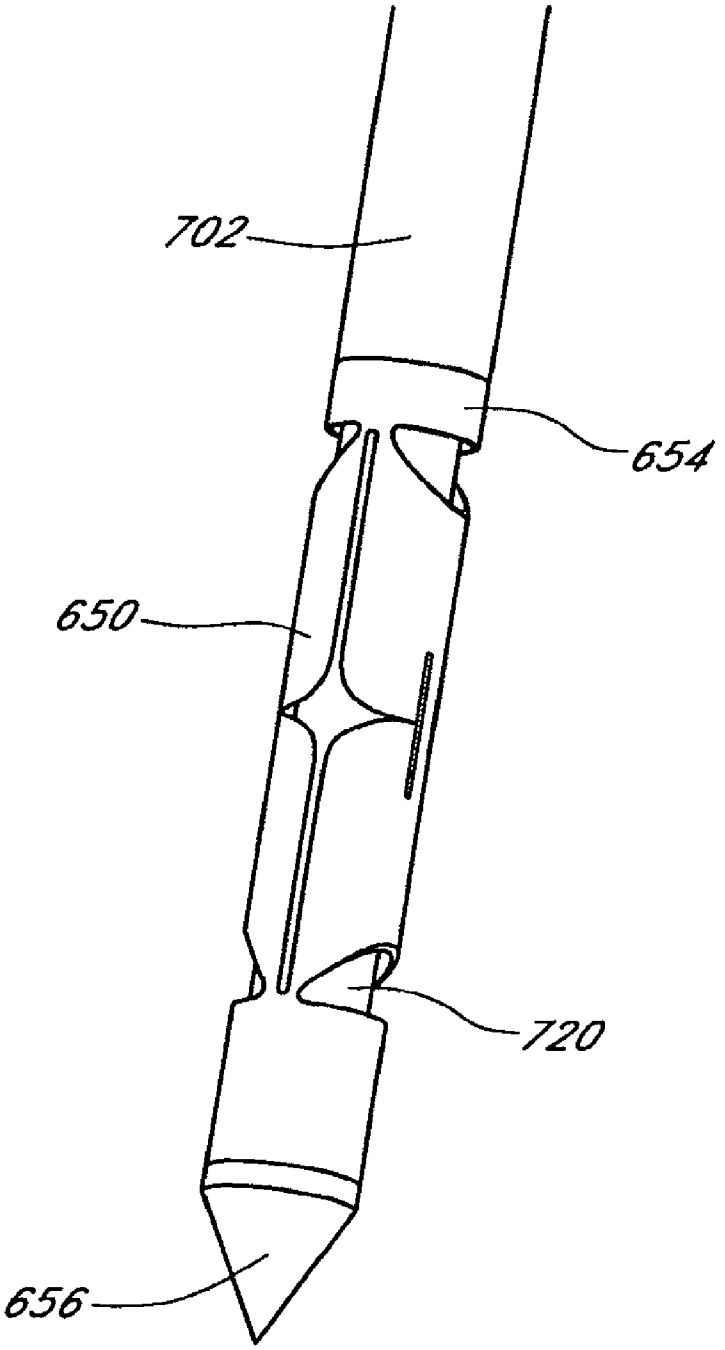

FIG. 13

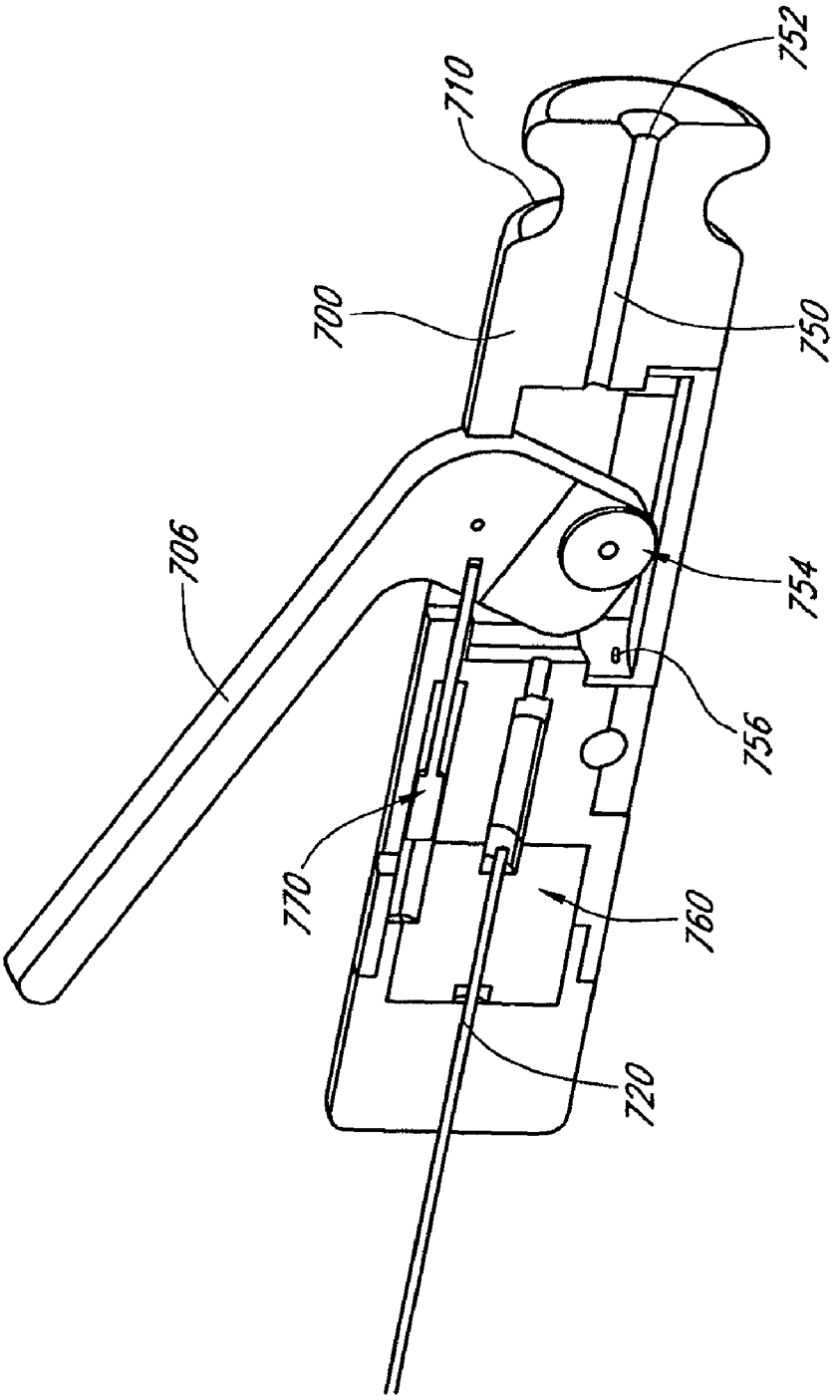

FIG. 14

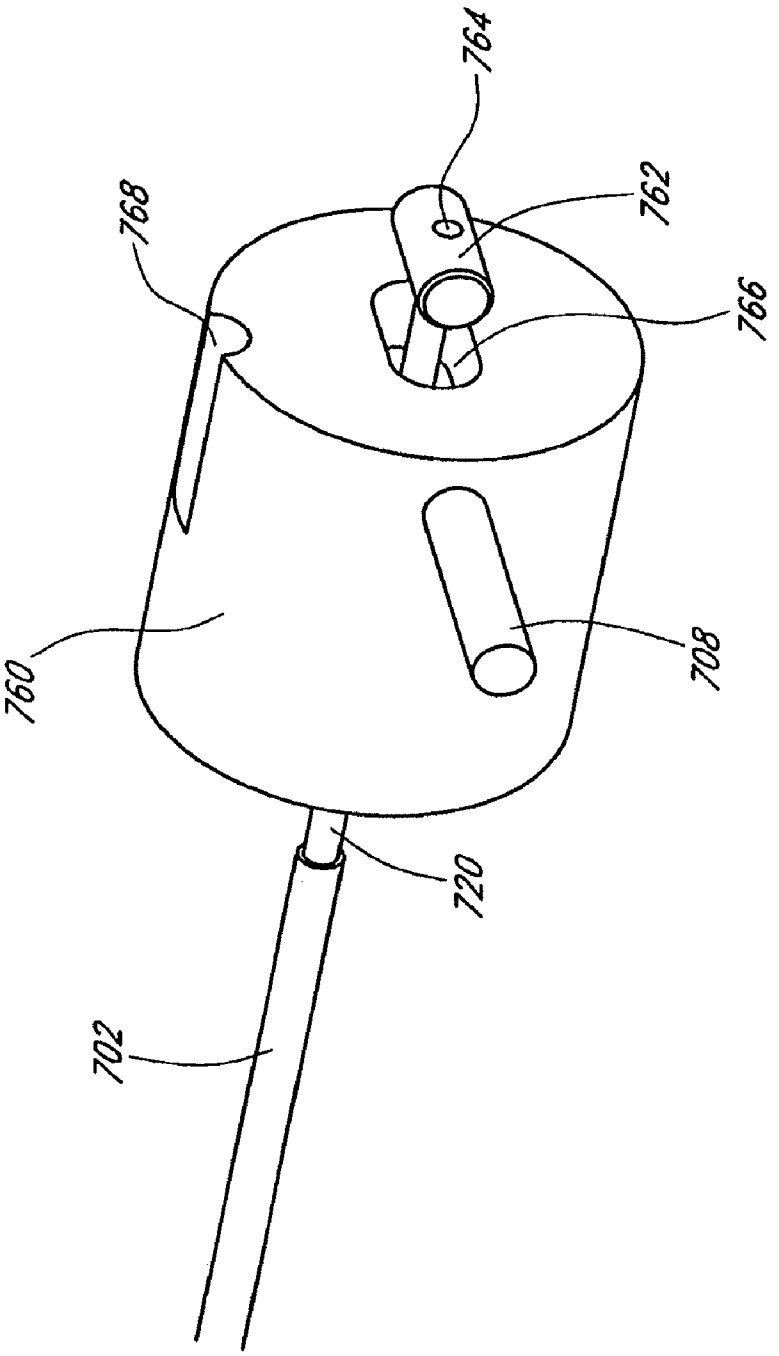

FIG. 15

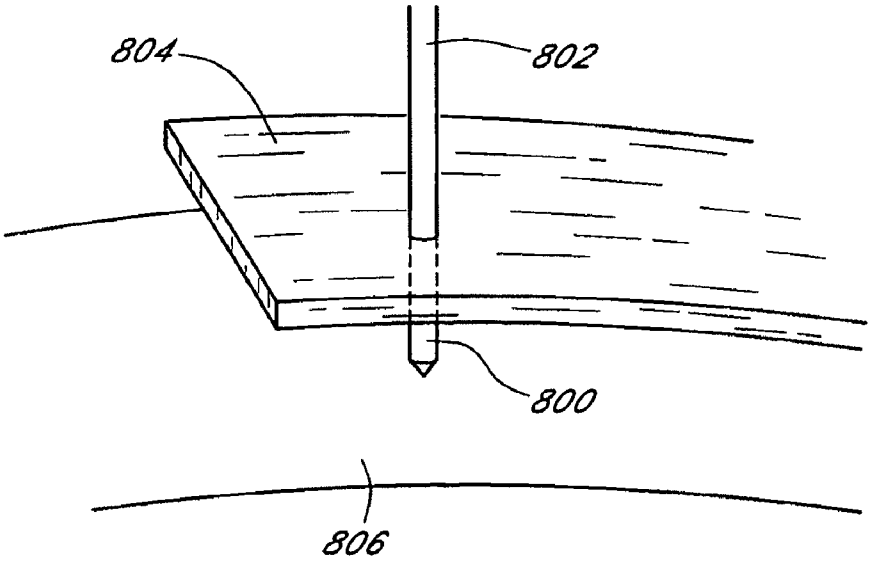

FIG. 16A

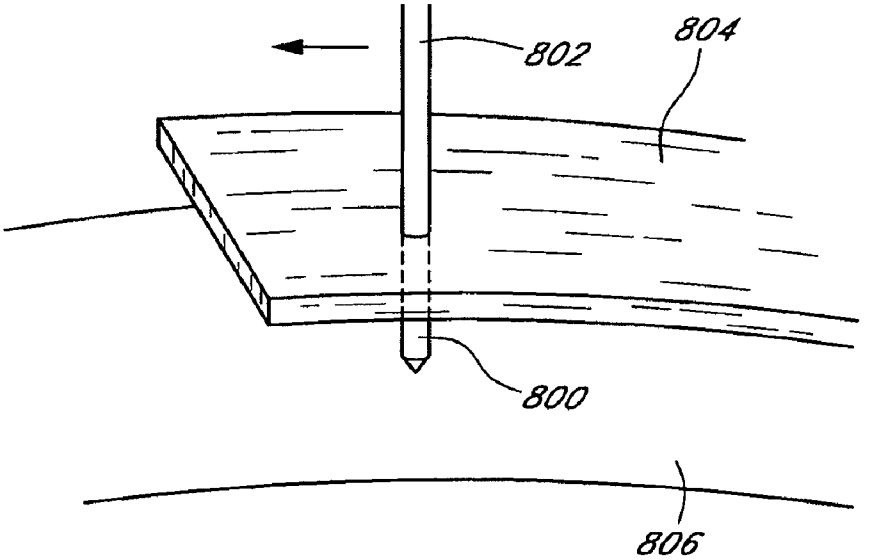

FIG. 16B

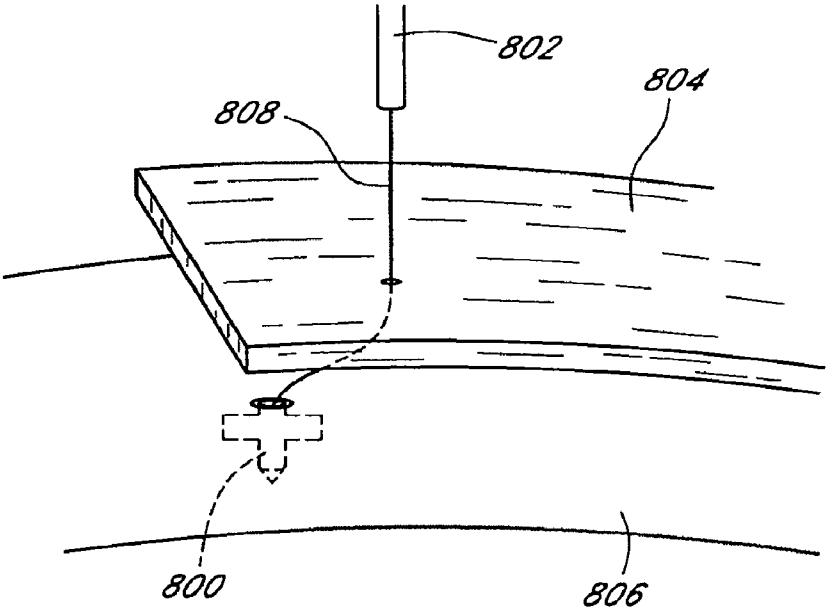

FIG. 16C

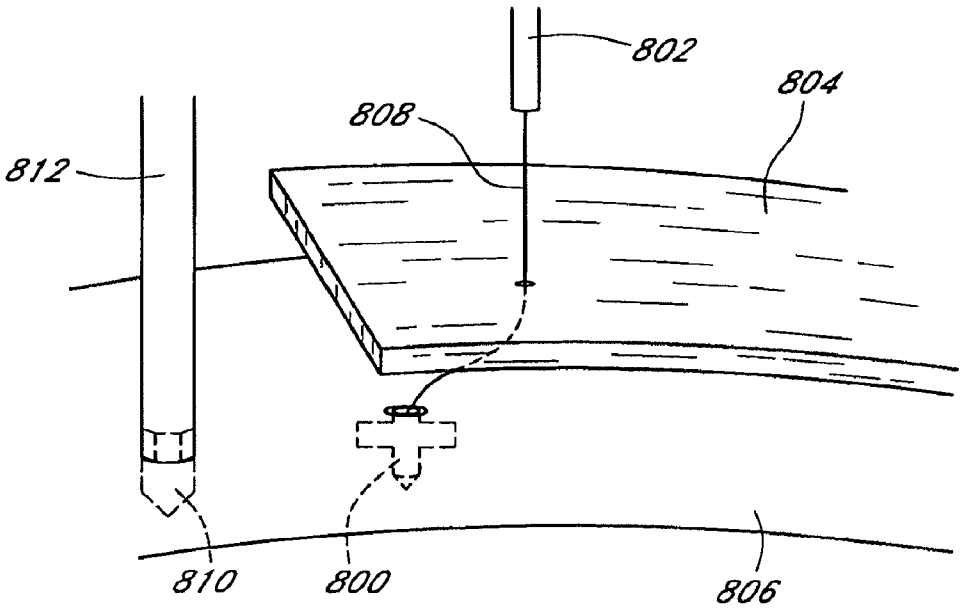

FIG. 16D

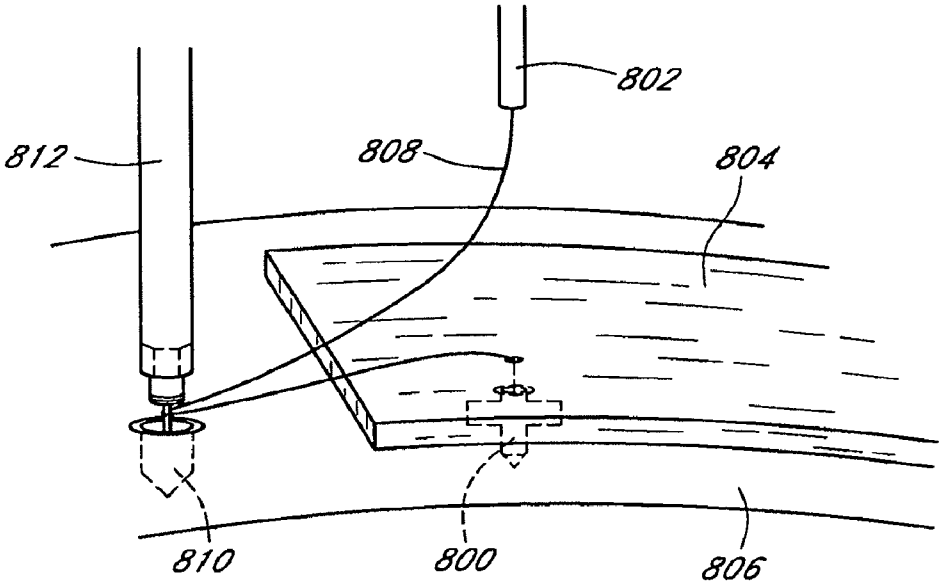

FIG. 16E

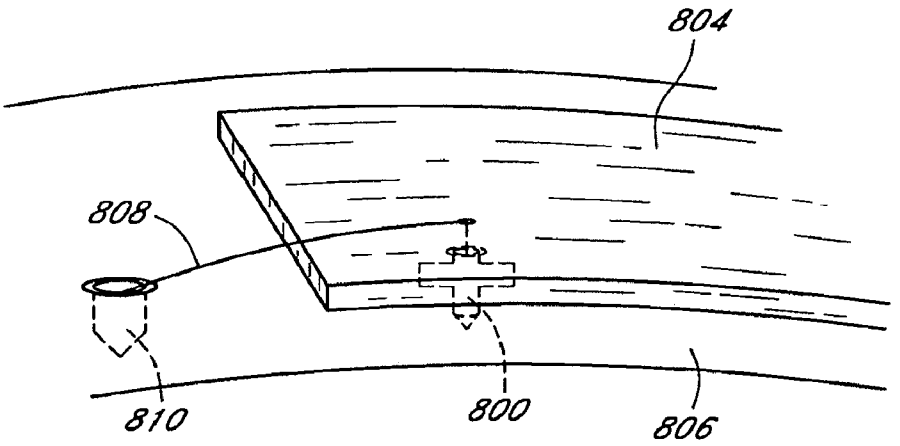

FIG. 16F

SYSTEM AND METHOD FOR ATTACHING SOFT TISSUE TO BONE

RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 12/549,105, filed Aug. 27, 2009, which is a divisional of U.S. application Ser. No. 11/143,007, now U.S. Pat. No. 7,585,311, filed Jun. 1, 2005, which claims priority to U.S. Provisional Application Nos. 60/576,477, filed on Jun. 2, 2004; 60/610,924, filed on Sep. 17, 2004; and 60/634,174, filed on Dec. 7, 2004; all of which are incorporated herein by reference in their entirety.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to medical devices and procedures. More particularly, the present invention relates to devices and methods for securing soft tissue to a rigid material such as bone.

2. Description of the Related Art

There are several medical procedures where a surgeon needs to attach soft tissue such as tendons or other soft connective tissue to bone. One common example is a torn rotator cuff, where the supraspinatus tendon has separated from the humerus causing pain and loss of ability to elevate and externally rotate the arm. To repair a torn rotator cuff, typically a surgical procedure is used to suture the torn tendon to the bone using a variety of methods. Some procedures utilize large incisions and involve complete detachment of the deltoid muscle from the acromion. Small diameter holes are made in the bone for passing suture material through the bone to secure the tendon. Such large incision procedures are traumatic, causing prolonged pain and recovery time. Other procedures make small incisions and use arthroscopic techniques to attach sutures using either small diameter holes or a bone anchor. However, it is difficult to manipulate sutures within the surgical site using arthroscopic techniques. In addition, when knot tying is used to secure the suture to a bone anchor, it is difficult to properly adjust the tension of the suture while tightening the knot. Similarly, when the suture is attached to a bone anchor prior to insertion of the anchor into the bone, it is difficult to judge the appropriate point of attachment so that the suture will be properly tensioned upon insertion of the bone anchor into the bone. Thus, there is a need for methods and devices that allow easy arthroscopic attachment of a suture to a bone anchor after the anchor is inserted into the bone without the use of knot tying.

SUMMARY OF THE INVENTION

The present invention is particularly suited for use in arthroscopic procedures, including but not limited to rotator cuff surgery. More broadly, it can be used in any procedure in which it is desired to fix a suture to a solid object without tying of knots, including not only arthroscopic procedures, but also open surgery, and can be used for such diverse purposes as bladder neck suspension, tendon and ligament affixation or repair, prosthetic attachment, and rotator cuff repair.

In one embodiment, the invention includes an anchor for securing a suture to bone, including an anchor base adapted to be securely fixed into the bone and a suture securing mechanism coupled to the anchor base and positioned proximally relative to the anchor base, the mechanism adapted to receive and secure a suture moved laterally into the

In another embodiment, the invention includes an anchor for securing a suture to bone, including an anchor base adapted to be securely fixed into the bone, a first surface coupled to the anchor base and positioned proximally relative to the anchor base, and a second surface coupled to the anchor base and positioned proximally relative to the anchor base, wherein the first and second surfaces are adapted to be relatively positioned in at least two configurations, one of the configurations such that a gap is present between the first and second surfaces so that the suture can be positioned between the first and second surfaces by moving the suture laterally into the gap, and the other of the configurations such that the first and second surfaces are in close proximity so that the suture can be securely clamped between the first and second surfaces.

In another embodiment, the invention includes a method of attaching soft tissue to bone, including passing a length of suture over the soft tissue, inserting an anchor into the bone, and securing the length of suture to the anchor after the inserting without passing an end of the length of suture through any aperture in the anchor and without tying any knots.

In another embodiment, the invention includes a method of attaching soft tissue to bone, including inserting a first anchor through the soft tissue, wherein the first anchor comprises a length of suture fixedly secured to the first anchor prior to insertion, inserting the first anchor into the bone, passing the length of suture over the soft tissue, and fixedly securing, after the passing, the length of suture to a second anchor.

In another embodiment, the invention includes a method of attaching soft tissue to bone, the soft tissue comprising a first surface adjacent to the bone's surface and a second surface opposite the first surface, the method including inserting a first portion of a length of suture into the second surface of the soft tissue, passing a second portion of the length of suture over the second surface of the soft tissue, inserting a first anchor with no suture coupled thereto into the bone, and fixedly securing the length of suture to the inserted first anchor, with the proviso that no part of the first portion of the length of suture is passed out of the second surface of the soft tissue.

In another embodiment, the invention includes a method of attaching soft tissue to bone, including inserting a first anchor with a length of suture pre-coupled thereto through the soft tissue, inserting the first anchor into the bone, inserting a second anchor with no suture coupled thereto into bone, passing the length of suture over the soft tissue, and fixedly securing the length of suture to the inserted second anchor.

In another embodiment, the invention includes a method of attaching soft tissue to bone, the method including inserting a first, second, and third anchor into the bone, fixedly securing a first length of suture over the soft tissue to the first and second anchors, and fixedly securing a second length of suture over the soft tissue to the first and third anchors.

In another embodiment, the invention includes an anchor for securing a suture to bone, the anchor including an anchor base adapted to be securely fixed into the bone, the anchor base comprising a first proximal surface and an anchor top, the anchor top comprising a distal member coupled to the anchor base and a first proximal member comprising a first distal surface, wherein the anchor top is adapted to couple to the anchor base in at least two configurations, one of the configurations such that the first distal surface is above the bone's surface when the anchor base is securely fixed into the bone, such that a suture can be freely passed between the first proximal and first distal surfaces above the bone's surface, and the other of the configurations such that the first distal

surface is in close proximity to the first proximal surface, such that a suture can be securely clamped between the first proximal and first distal surfaces.

In another embodiment, the invention includes an anchor for securing a suture to bone, the anchor including a substantially hollow cylinder comprising an open end and comprising a portion of its walls cut in such a manner so as to allow the cylinder to deform under stress and form lateral protrusions, a substantially pointed tip coupled to the cylinder opposite the open end, wherein the pointed tip is adapted to pierce the bone, and a suture receiver coupled to the pointed tip and positioned within the substantially hollow cylinder so that a suture may be attached to the suture receiver and extend through the cylinder and out of the open end.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** depicts attaching soft tissue to bone using a single bone anchor and a stitch.

FIG. **2** depicts attaching soft tissue to bone using a two bone anchors with a suture stretched there between.

FIGS. **3**A-**3**C depict various geometries of bone anchors and suture patterns for attaching soft tissue to bone.

FIGS. **4**A-**4**D depicts the base of a two-part suture anchor that can be inserted into bone.

FIGS. **5**A-**5**C depicts the top of a two-part suture anchor.

FIGS. **6**A and **6**B depict the suture anchor top of FIGS. **5**A-**5**C inserted into the suture anchor bottom of FIGS. **4**A-**4**D.

FIGS. **7**A and **7**B depict a suture anchor inserter.

FIG. **8** depicts components on a suture anchor inserter for attaching to bone and manipulating a suture anchor.

FIGS. **9**A-**9**E depicts manipulation of a suture anchor using a suture anchor inserter to insert the suture anchor into bone and attach suture material to the suture anchor.

FIGS. **10**A and **10**B depict a piercing bone anchor in an un-deployed (FIG. **10**A) and deployed (FIG. **10**B) state.

FIG. **11** depicts a piercing bone anchor tip.

FIG. **12** depicts an anchor inserter for inserting a piercing bone anchor.

FIG. **13** depicts the interface between a piercing bone anchor and an anchor inserter.

FIG. **14** is a cut-away view of a bone anchor inserter.

FIG. **15** depicts a safety switch mechanism for a bone anchor inserter.

FIGS. **16**A-**16**F depict a method for attaching soft-tissue to bone using a piercing bone anchor and a suture capturing anchor.

DETAILED DESCRIPTION OF THE CERTAIN EMBODIMENTS

In various embodiments, soft tissue may be attached to bone utilizing one or more bone anchors with suture attached thereto. As used herein, "suture" refers to any flexible structure that can be stretched between two or more anchors and includes, without limitation, traditional suture material, single or multiple stranded threads, or a mesh structure. In some embodiments, suture is passed over the top of the soft tissue so that the suture can press the soft tissue against the bone. In one embodiment, a length of suture is attached to a single bone anchor. One non-limiting example, depicted in FIG. **1**, includes stitching the suture **10** to the soft tissue **12**, such as by an incline mattress stitch, and then securing the suture **10** to the single bone anchor **14** that is inserted into the bone **16**. However, in other embodiments, a length of suture is attached to multiple bone anchors. The use of multiple bone anchors increases the footprint over which the suture material presses the soft tissue against bone. One non-limiting example, depicted in FIG. **2**, includes two bone anchors. One anchor **20** is positioned in a medial location underneath the soft tissue **12** and a second anchor **22** is positioned lateral to the soft tissue **12**. The suture **10** is attached to both anchors.

In one embodiment, the suture **10** is attached to the lateral bone anchor **22** only after the medial bone anchor **20** is inserted and the suture **10** is passed over the soft tissue **12**. In one embodiment, the suture **10** is attached to the medial bone anchor **20** prior to insertion of the medial bone anchor **20**. Thus, in this embodiment, the surgeon does not need to pass the suture through the soft tissue **12** from beneath the soft tissue **12**. In one embodiment, the procedure involves inserting the medial bone anchor **20** with suture **10** pre-attached through the soft tissue **12**. The medial bone anchor **20** may then be moved laterally relative to the bone **16** in order to pull the soft tissue **12** laterally relative to the bone **16**. After appropriate positioning of the soft tissue **12**, the medial bone anchor **20** may then be inserted into the bone **16**. The lateral bone anchor **22** may then be inserted into the bone **16**. The suture **12** may then be passed over the soft tissue **12** and attached to the lateral bone anchor **22**. In some embodiments, a lateral bone anchor **22** is provided to which suture **12** can be attached without tying any knots or without passing the suture **12** through any aperture in the lateral bone anchor **22**.

In some embodiments, multiple anchors and multiple suture lengths may used to provide a wider area of pressure of the soft tissue against bone. For example, as depicted in FIG. **3**A, three anchors are used with two lengths of suture **26** and **28**. Alternatively, a mesh structure **29** may be stretched between the three anchors. In another example, as depicted in FIG. **3**B, four anchors are used with two lengths of suture. In still another example, as depicted in FIG. **3**C, four anchors are used with four lengths of suture. In some embodiments, the individual suture lengths may be part of a larger continuous suture. For example, in FIG. **3**A, the suture lengths **26** and **28** may be part of a larger length of suture such that the lengths **26** and **28** are joined at medial bone anchor **20**. Those of skill in the art will appreciate that there are any number of anchor and suture geometries that can be used.

In some embodiments, the medial bone anchors **20** are designed so that they can be easily pierced through the soft tissue **12** and bone **16**. In some embodiments, the lateral bone anchors **22** are designed so that they can easily capture suture material after insertion of the bone anchors **22**. Together, these design features provide a suturing system and method that provides an increased footprint of suture pressure against the soft tissue **12** and ease of implementation for a surgeon. For example, in some embodiments, the entire procedure may be done arthroscopically, with the surgeon needing only to insert the medial bone anchor **20** with suture optionally pre-attached through a first port, insert the lateral anchor **22** through a second port, pass the suture over the soft tissue **12** by capturing it from within the second port, and securing the suture to the lateral anchor **22**. Accordingly, described below are certain embodiments of anchors adapted to capture suture material and anchors adapted to easily pierce through soft tissue and bone.

Suture Capturing Anchor

One embodiment is a bone anchor that allows easy capturing and securing of a suture after the bone anchor is inserted into the bone. In one embodiment, the bone anchor includes a suture securing mechanism positioned on the proximal end of the bone anchor (i.e., the end nearest the surface of the bone and the surgeon). In one embodiment, the suture securing mechanism allows a suture to be moved laterally into the

mechanism. By "laterally," it is meant that the suture can be moved into the mechanism by moving the suture in a direction that is generally perpendicular to the axis of the suture. In other words, the suture can be moved into the mechanism without threading an end of the suture into the mechanism. In one embodiment, the suture can be fixedly secured within the mechanism without tying any knots. By "fixedly secured," it is meant that the suture within the securing mechanism cannot be easily moved relative to the bone anchor.

One embodiment is a bone anchor that allows easy attachment of suture material by clamping the suture material between two surfaces on the bone anchor. The bone anchor may be configured such that the bone anchor is inserted into the bone without the suture material attached. The two surfaces of the suture securing mechanism may be spaced apart so as to form a gap between the surfaces. The suture material may be passed between the two surfaces and tensioned as desired followed by clamping of the two surfaces together, thereby clamping the suture material there between.

In one embodiment, the bone anchor consists of two parts: an anchor base and an anchor top. The anchor base may be designed to be inserted into a hole in the bone with a proximal surface facing up. The anchor top may be coupled to the anchor base via a distal member. A proximal member on the anchor top may have a distal surface facing down toward the proximal surface on the anchor base. The coupling of the anchor top to the anchor base may be such that the anchor top can move relative to the anchor base such that it can be positioned in one configuration where there is space between the proximal surface on the anchor base and the distal surface on the proximal member of the anchor top. In another configuration, the proximal member of the anchor top may be position such that there is very little space, if any, between the proximal surface on the anchor base and the distal surface on the proximal member of the anchor top. Thus, in the first configuration, suture material may be easily passed between the two surfaces and tensioned as desired. In the second configuration, the suture material may be clamped between the two surfaces such that the suture is secured to the bone anchor.

One embodiment of an anchor base **100** is depicted in FIGS. **4**A through **4**D. FIG. **4**A is a perspective view showing the side **101** and bottom **102** of the anchor base **100**. The bottom **102** of the anchor base **100** may advantageously be tapered to facilitate insertion of the anchor base **100** into bone. In some embodiments, a hole is predrilled into the bone to facilitate insertion of the anchor base **100**. In other embodiments, the anchor base **100** is forced directly into the bone, thereby creating the hole. The sides **101** of the anchor base **100** comprise threads **104** so that the anchor base **100** may be inserted into bone using a screwing action. In some embodiments, the anchor base **100** may be tapped to start the threads **104** into the bone followed by screwing the anchor base **100** into the bone. When the hole in the bone is pre-drilled, the hole is advantageously drilled with a diameter smaller than the diameter of threads **104** so that the threads engage the bone through the sides of the hole. It will be appreciated that means other than threads may be used to secure the anchor base **100** to bone. For example, angled protrusions may be used that provide greater resistance to removal of the anchor base **100** than to insertion. The protrusions may be static or deployable once the anchor is inserted.

The top of anchor base **100** preferably includes a structure **106** for facilitating the driving or screwing of the base **100** into the bone. In the illustrated embodiment, this comprises a hex nut structure **106** that facilitates engagement with a hex nut driver for screwing the anchor base **100** into the bone. It will be appreciated that other structures known in the art for engaging tools used for screwing action may be used instead of hex nut structure **106**, and that this structure can be indented into or extending out from the top of the anchor base **100**, or can alternatively be formed on the sides of the anchor base **100**.

With reference to FIG. **4**B, which is a perspective view of the top and side of anchor base **100**, the top (proximal end) comprises a hole **108** in the center for receiving the anchor top, which is described below. The top of anchor base **100** also contains a suture gripping structure such as a circular groove **110** that may be concentric with hole **108**. Because of groove **110**, the proximal surface of anchor base **100** is not flat and comprises top surfaces **112** and **114**, bottom surface **116**, and side surfaces **118** and **120**. In some embodiments, some or all of these surfaces may be textured such as with a scallop shape or grooves so as to inhibit movement of suture material pressed against the surfaces. Although a grooved surface is illustrated, it will be appreciated that other shapes for the proximal surface of anchor base **100** are also contemplated, including multiple concentric grooves, a series of protruding ridges, a "vee" shaped channel, or any other suitable structure that permits a suture to be securely locked against the top or proximal end of the anchor base **100**.

Hole **108** in anchor base **100** is an opening into a central ("axial") bore into the anchor base **100**. The sides of the central bore preferably include structures for gripping something inserted into the central bore, such as ratchet structures **122**. FIG. **4**C show a central ratchet bushing **126** that fits within the central bore and contains the ratchet structures **122**. In the embodiment of FIG. **4**C, the ratchet structures **122** are constructed by cutting U shaped cuts into bushing **126**. The U shaped cuts then define tabs that make up the ratchet structures **122**. It will be appreciated that other shapes and methods for making ratchet structures may be used. The purpose of ratchet bushing **126** is to receive the anchor top and secure it to the anchor base **100**. It will be appreciated that other methods of securing the anchor top to the anchor base **100** may be used, such as a frictional fit or threading. Furthermore, the anchor top may be coupled to the anchor base **100** using means other than hole **108** and bushing **126**. For example, the anchor top may be coupled via structures at the perimeter rather than the center or by a hinge.

FIG. **4**D depicts a cross section through the center of anchor base **100**. This view illustrates central bore **130** and groove **110**. The proximal surfaces **112**, **114**, **116**, **118**, and **120** are also apparent. Central bore **130** preferably does not extend all the way through the anchor base **100**. Instead, a smaller bore **132** is present at the distal end **102** of the anchor base **100**. Smaller bore **132** is used to receive a wire connected to an anchor inserter. It will be appreciated that other structures than bore **132** may be used for attaching the wire and that other means than a wire may be used to secure the anchor to the anchor inserter.

FIGS. **5**A through **5**C illustrate one embodiment of an anchor top **200**. FIG. **5**A provides a perspective view of the side and top of the anchor top **200** and FIG. **5**B provides a perspective view of the side and bottom of the anchor top **200**. Anchor top **200** has two members, a distal member **202** and a proximal member **204**. The distal member **202** comprises an elongated shaft, the longitudinal direction of which shall be considered to run along the axis of the distal member **202**. A series of grooves or other mating or locking surfaces or structures **206** exist along a portion of the outside surface of the shaft. The distal member **202** is designed to be inserted into the central bore **130** of the anchor base **100**. The ratchet structures **122** in the anchor base **100** engage grooves **206** to

couple the anchor top **200** to the anchor base **100**. The ratchet structures **122** are oriented such that the distal member **202** can be easily moved in the distal direction in central bore **130** with the ratchet structures **122** snapping into the grooves **206** as the distal member **202** is moved downward. However, when the ratchet structures **122** are snapped into grooves **206**, proximal movement of distal member **202** is inhibited. Thus, the anchor top **200** may be ratcheted down into anchor base **100**. Because the ratchet structures **122** exist along substantially the entire surface of the central bore **130** (see FIG. **4**C), the anchor top **200** may be coupled to the anchor base **100** in several positions. In other words, in one embodiment the anchor top **200** need not be ratcheted into the anchor base **100** as far as it will go for it to be secured to the anchor base **100**.

The proximal member **204** of anchor top **200** is generally cylindrical in shape with a diameter larger than distal member **202**. A hole **208** may advantageously be provided in the center of proximal member **204**. With reference to FIG. **5**B, the bottom of distal member **202** also contains a hole **210**. Holes **208** and **210** open into a central bore through the anchor top **200**. This central bore allows the wire referred to above to extend through the anchor top **200** to be secured to bore **132** in the anchor bottom **100**, thus allowing the anchor bottom **100** to be attached to an anchor inserter while still allowing anchor top **200** to be ratchet into anchor bottom **100**. FIG. **5**B also illustrates that proximal member **204** contains a groove **212** in its distal surface. Thus, the distal surface of proximal member **204** is not flat and comprises distally facing surfaces **214** and **216** and side facing surfaces **218** and **220**. In some embodiments, some or all of these surfaces may be textured such as with a scallop shape or grooves so as to inhibit movement of suture material pressed against the surfaces. In some embodiments, texturing in the distal surfaces of proximal member **204** match texturing in the proximal surfaces of anchor base **100**. It will be appreciated that the illustrated embodiments represent only one possibility; thus, other shapes for the distal surface of proximal member **204** may also be used. FIG. **5**C depicts a cross section through the center of anchor top **200**. In this figure, the central bore **226** is depicted as are surfaces **214**, **216**, **218**, and **220** and grooves **206**.

FIGS. **6**A and **6**B depict cross sections showing how the anchor top **200** may be coupled to anchor base **100** to form the complete anchor **300**. In FIG. **6**A, the anchor top **200** is coupled to anchor base **100** with the proximal member **204** separated from the anchor base **100**. The anchor top **200** is secured to anchor base **100** by distal member **202** extending into central bore **130** of the anchor base **100**. The distal member **202** is secured by ratchet structures (not shown) engaging grooves **206** in distal member **202**. Central bore **226** in anchor top **200** and central bore **130** in anchor base **100** allow a wire to extend into the top of the anchor **300** and be secured to bore **132**. Alternatively, the wire may be secured at other locations within central bore **130**. Thus the wire, which can be coupled to an anchor inserter, can hold the entire anchor assembly **300** and still allow anchor top **200** to move relative to anchor base **100** and the wire.

FIG. **6**B depicts the anchor assembly **300** with the distal member **202** of anchor top **200** ratcheted all the way into central bore **130** in anchor base **100**. In this configuration, it can be seen that proximal surfaces **112**, **114**, **116**, **118**, and **120** of the anchor base **100** and distal surfaces **214**, **216**, **218**, and **220** of the proximal member **204** of anchor top **200** form passageways **302** and **304**. The size of passageways **302** and **304** are advantageously such that when a suture passes through them, it will be compressed so that it is securely attached to the anchor **300**.

Another embodiment of the present invention is an inserter designed to insert and manipulate an anchor such as described in FIGS. **1**-**3**. One such inserter **400** is depicted in FIGS. **7**A and **7**B. Inserter **400** comprises a handle **402** and an outer tube **404**. As depicted in FIG. **7**A, the handle **402** comprises a cover **403**. FIG. **7**B depicts the inserter **400** with cover **403** removed. Not depicted in FIGS. **7**A and **7**B are an inner tube disposed inside outer tube **404** and a wire disposed within the inner tube. As will be described in more detail below, the inner and outer tubes may be used to manipulate an anchor **300** such as that described in FIGS. **4**-**6**. The wire may be used to couple the inserter **400** to the anchor **300** as described above. Inserter **400** also comprises an outer tube manipulator **406** and a wire manipulator **408**. Outer tube manipulator **406** comprises release button **410**. Outer tube manipulator **406** is securely attached to outer tube **404**. Outer tube manipulator **406** may move longitudinally relative to handle **402** and the inner tube when release button **410** is pressed. Thus, when outer tube manipulator **406** is moved, outer tube **404** also moves.

Wire manipulator **408** comprises wire grabber **410** to which the wire is attached. The wire extends from wire grabber **410**, through handle **402**, and then through the inner tube. In one embodiment, wire manipulator **408** also comprises a release button **412**. When release button **412** is pressed, the wire manipulator **408** may be pressed into the handle **402** to contact and thus provide additional tension on the wire. When in use, the additional tension causes the anchor base **100** to mover relative to inserter **400**. When enough tension is provided to the wire by wire manipulator **408**, the wire may break free from the anchor **300** at its attachment point in bore **132** or at some other predetermined location along the wire. It will be appreciated that any suitable breakable attachment means may be used for securing the wire to the anchor **300**. For example, the wire may be frictionally secured into bore **132** or it may welded to the anchor base **100** using a weld that is weaker than the wire itself or a portion of the wire where breaking is desired may be weakened. In one embodiment, the wire is notched so as to create a weaker region in the wire that will break upon application of suitable force.

The tip **414** of outer tube **404** is depicted in more detail along with inner tube **420**, wire **422**, and anchor **300** in FIG. **8**. The end of outer tube **404** may comprise a hex nut driver structure **424** for receiving the hex nut structure **106** of anchor base **100**. Of course, any other suitable engagement structure can be provided on the inserter **400** and the anchor base **100** in order to facilitate placement of the anchor base **100**. Wire **422** extends out of inner tube **420** and into the central bore in the anchor top **200** to attach to anchor base **100** as described above. In some advantageous embodiments, the wire length and tension is adjusted such that the proximal member **204** of anchor top **200** buts against the end **426** of inner tube **420**.

FIGS. **9**A through **9**E depict how inserter **400** and anchor **300** may be used to insert the anchor **300** into bone and attach a suture to it. FIG. **9**A depicts the configuration for inserting the anchor **300** into bone. Outer tube **404** and outer tube manipulator **406** (see FIGS. **7**A and **7**B) are positioned relative to inner tube **420** and handle **402** (see FIGS. **7** and **8**) so that the outer tube **404** engages hex nut structure **106** in the anchor base **100**. It is advantageous in this configuration for the anchor top **200** to be in a position relative to the anchor base **100** such as depicted in FIG. **6**A. In the configuration of FIG. **9**A, a surgeon may then screw the anchor base **100** into bone by twisting handle **402** of inserter **400** (see FIGS. **7**A and **7**B).

After the anchor base **100** is inserted into the bone, the outer tube **404** may be slid backward relative to the inner tube **420** and handle **402** to expose the anchor top **200** such as in

FIG. **9**B. One or more lengths of suture **600** may then be placed in the space between the distal surface **602** of the proximal member **204** of anchor top **200** and the proximal surface **604** of the anchor base **100** by moving the suture laterally into the space as depicted in FIG. **9**C. The suture **600** may be manually tensioned as desired. In some embodiments, tensioning of the suture **600** is aided by pulling the suture **600** against the distal member **202** of the anchor top **200**.

After appropriate tensioning of suture **600**, wire manipulator **408** may be pressed to tension the wire, causing the handle **402** of the inserter **400** and the inner tube **420** to be pulled down towards the anchor base **100** so that inner tube **420** ratchets the anchor top **200** down into the anchor bottom **100** as depicted in FIG. **9**D. As the anchor top **200** is pushed axially down, suture **600** will be clamped between the distal surface **602** of the proximal member **204** of anchor top **200** and the proximal surface **604** of the anchor base **100** (see also FIG. **9**C). The clamping will force the suture to be compressed within the passageways **302** and **304** depicted in FIG. **6**B and thus be secured to anchor **300**. The fit between the anchor top **200** and the anchor base **100** in the clamping region is such that the suture **600** is firmly gripped, but is not cut, when it is clamped in place. Appropriate edges that may contact the suture are preferably beveled or rounded to avoid damage to the suture. After anchor top **200** is ratcheted sufficiently into anchor base **100**, wire manipulator **408** (see FIGS. **7**A and **7**B) in inserter **400** may be compressed further to further tension wire **422** (see FIG. **8**) such that wire **422** breaks free from its attachment to anchor base **100**, thus leaving the anchor **300** free from inserter **400** with suture **600** securely attached as depicted in FIG. **9**E.

Although a particular inserter device for inserting and manipulating anchor **300** has been described, it should be understood that other inserter designs may be used for manipulating the parts of anchor **300** described above to insert the anchor into bone and secure suture material to the anchor. For example, it may be possible to use separate tools for inserting the anchor and securing the suture material. In addition, in alternative embodiments, the anchor base **100** may be connected to the anchor top **200** throughout the procedure, or the anchor base may be separately inserted into the bone, and the anchor top can be attached thereafter by axially sliding the distal end of the anchor top **200** into the hole **108** in the anchor base **100**.

It will be appreciated by those of skill in the art that the anchor **300** and inserter **400** provide a system for easy attachment of a suture to bone. The anchor **300** may be inserted into bone with minimal disruption of surrounding tissue. Only an access route having the diameter of the outer tube **404** and the anchor base **100** is required. Furthermore, the suture can be securely attached to the anchor **300** and tensioned as desired without having to insert additional instrumentation into the site or without performing any cumbersome attachment maneuvers such as knot tying. It should also be appreciated that the general principle illustrated by this system of inserting an anchor into bone without having suture material pre-attached and then attaching suture to the anchor without tying any knots may be implemented using any appropriate system other than the specific embodiments depicted in FIGS. **4**-**9**.

Tissue and Bone Piercing Anchor

One embodiment is a bone anchor adapted for piercing through the soft tissue and into underlying bone. In one embodiment, the suture material may be pre-attached to the piercing bone anchor so that after implantation, a suture passes from the bone anchor through to the top of the soft tissue for easy passing over the soft tissue. In one embodiment, the piercing bone anchor has two configurations, a first configuration having a small diameter for easy piercing through soft tissue and bone and a second deployed configuration where structures such as protrusions are deployed to prevent the bone anchor from being easily removed from the bone.

In one embodiment, the anchor includes a substantially hollow cylinder having a portion of its walls cut in such a manner so as to allow the cylinder to deform under axial stress and form lateral protrusions. The lateral protrusions may thus prevent the anchor from being easily removed from the bone after deployment. In one embodiment, the anchor comprises a pointed tip coupled to the hollow cylinder for piercing the soft tissue and bone. In one embodiment, suture is pre-attached to the pointed tip inside of the hollow cylinder. In other embodiments, suture is pre-attached at other locations on the piercing anchor, such as at the proximal end of the hollow cylinder.

One embodiment of a deployable piercing anchor is depicted in FIGS. **10**A and **10**B. In FIG. **10**A, the anchor is depicted in a pre-deployed state. The anchor includes a substantially hollow cylinder **650** with a plurality of cuts **652** in the side of the cylinder **650**. The cylinder **650** is open on one end **654**. On the other end, a pointed tip **656** is disposed, allowing the anchor to pierce through soft tissue and bone. In FIG. **10**B, the anchor is depicted in a deployed state. Stress is applied in an axial direction such that the cylinder **650** collapses along cuts **652** so as to form two lateral wings **660**. The lateral wings **660** prevent the anchor from being removed from the bone. Hinges **662** connect one end of each wing to either the top or the bottom parts of anchor body. These hinges deform and fold, in the plane tangent to the anchor body at that point when the anchor is deployed. A strip of material **664** connects the top and bottom wing on each side of the anchor body, and serves as a hinge between the two as well as aiding in alignment of the wings during deformation. The tips of the wings adjacent to the connecting strip **664** utilize rolling edges **666**, which ensure uniform alignment and smooth transition during deformation. Those of skill in the art will appreciate that any number of geometries of cuts in the cylinder **650** may be utilized to create a deformable structure that will produce lateral protrusions upon exposure to stress.

In some embodiments, structures may be positioned within the cylinder **650** for attaching sutures and engaging with an anchor inserter. In one embodiment, such structures are coupled to the anchor tip **656** within the cylinder **650**. FIG. **11** depicts one such embodiment. Attached to the tip **656** is a structure **670** through which there is an aperture **672**. The structure **670** may be adapted to engage the inner surface of cylinder **650** for attaching the tip **656** to the cylinder **650**. The attachment mechanism may be by forced fit, frictional fit, threads, welding, adhesive, or any other suitable means. Suture material may be threaded through the aperture **672** in order to attach the suture to the anchor. The suture material may be secured to the tip **656** by tying the suture around structure **670**, tying a knot in the end of the suture that prevents it from being pulled through the aperture **672**, clamping the suture between the structure **670** and the inside of the cylinder **650**, adhering the suture to structure **670** by welding or adhesive, or any other suitable means. In one embodiment, the suture material is attached to the anchor at tip **656** prior to use of the anchor.

An anchor inserter attachment structure **674** may also be coupled to the tip **656**. This structure **674** may couple to an anchor inserter through a wire or any other suitable means. The attachment between the anchor inserter and the anchor at this point may be used to apply axial stress to the anchor for

deploying the anchor as described above. The attachment at this point may also serve to keep the anchor attached to the inserter prior to deployment.

One embodiment of an anchor inserter suitable for use with the above-described anchor is depicted in FIG. **12**. The anchor inserter comprises a grasping handle **700** to which is attached an outer sleeve **702** which is fixed relative to the handle **700**. The piercing anchor **704** is disposed at the end of the sleeve **702**. A deployment lever **706** may be pressed by a user to deploy and detach the anchor **704** as described below. A safety switch **708** may be provided to prevent the anchor **704** from being deployed prematurely. A spool **710** may be provided at the proximal end of the handle **700** for holding excess suture. A lid **712** may be provided for gaining access to the inner components of the inserter.

FIG. **13** depicts the anchor **704** coupled to the inserter. As described above, the anchor **704** comprises a hollow cylinder **650** with cuts in the sides and a pointed tip **656**. Furthermore, as depicted in FIG. **11**, a suture receiving aperture **672** and an inserter attachment structure **674** are attached to the pointed tip **656** within the cylinder **650**. The outer sleeve **702** of the inserter may fit over the open end **654** of the cylinder **650** or be flush with the open end **654**. The outer sleeve **702** may thus hold the top part of the anchor **704** steady during insertion. In an alternative embodiment, the outer sleeve **702** may fit over the length of the cylinder **650** to prevent the cylinder **650** from deforming while it is being inserted into bone. In this alternative embodiment, the outer sleeve **702** may be retracted prior to deployment of the anchor. An inner tube **720** may be positioned within the outer sleeve **702** and the hollow cylinder **650** and contact the top surface of the anchor tip **656** (see FIG. **11**). The inner tube **720** provides structural reinforcement of the anchor **704** and pushes against the tip of the anchor **704** while it is being driven into bone or tissue. The inner tube **720** may be fixed relative to the handle **712** and outer sleeve **702** during insertion, however, during deployment of the anchor **704**, the inner tube **720** may be released by switching safety switch **708** so that the inner tube **720** can move axially relative to the outer sleeve **702** while the anchor cylinder **650** collapses. A wire may be positioned inside of the inner tube **720** running from within the handle **712** through the inner tube **720** to the anchor **704** and attached to the anchor inserter attachment structure **674**. During deployment, the lever **704** may be pressed to pull the wire axially towards the handle **700**. The axially movement of the wire forces the anchor **704** to press against outer sleeve **702** and stresses the cylinder **650**, causing it to deform and deploy. During collapse of the cylinder **650**, the inner tube **720** will also move in an axial direction toward the handle **700**. Upon further stress on the wire, the wire may break free from the anchor inserter attachment structure **674**, releasing the inserter from the anchor **704**. Suture material may run from the inside of handle **700** through the inner tube **720** to attach to the anchor **704** through aperture **672** (see FIG. **11**). Upon detachment of the anchor inserter from the anchor **704**, the inserter may be withdrawn, leaving the inserted and deployed anchor with suture coming out of the open end **654** of the cylinder **650**. The suture will still be coupled to the inserter through the inner tube **720**, handle **700**, and around spool **710**. Those of skill in the art will appreciate other inserters and mechanisms that may be used to insert and deploy the piercing anchors described herein. For example, rather then axially stressing the anchor **704** by pulling the tip **656** in an proximal direction, the cylinder **650** may be pushed in a distal direction to deform the cylinder **650**.

FIG. **14** is a cut-away view of the handle **700**, showing the inner workings of the anchor inserter. The suture material attached to a piercing anchor at the tip of the inserter may pass through the central bore of the inner tube **720** and through a bore **750** in the handle **700**. The suture material may then pass through a hole **752** in the end of the handle **700** and be wrapped around the spool **710**, which may be integral with the handle **700**. The wire attached to the anchor inserter attachment structure **674** in the anchor may also pass through the central bore of the inner tube **720** and may then proceed around a pulley **754** and attach securely to the handle **700** at point **756**. The pulley **754** may be attached to the lever **706**. When the lever **706** is pressed down, the pulley **754** will move toward the back end of the handle **700**, causing the wire attached to the anchor to retract. Because of the use of pulley **754**, the wire will retract twice the distance as the pulley **754** moves.

The safety switch **708** may be used to prevent the lever **706** from being pressed and prevent the inner tube **720** from moving unless the safety switch **708** is in the correct position. The safety mechanism operates via a drum **760** disposed within the handle **700** to which the safety switch **708** is attached. Moving the safety switch **708** rotates the drum **760** within the handle **700**. FIG. **15** shows the drum **760** and safety switch **708** mechanism in more detail. The inner tube **720** passes through a central bore in the drum **760**. On the other side of the drum **760**, the inner tube **720** is attached to a stopper **762**. The stopper **762** has a through-hole **764** to permit passage of the deployment wire and suture. The stopper **762** may be positioned within a cavity **766** in the end of the drum **760**. A second similarly shaped cavity may be disposed within the handle **700**. The stopper **762** and attached inner tube **720** may only be allowed to move axially relative to the handle **700** when the safety switch **708** and drum **760** is rotated so that the cavity **766** in the drum **760** is aligned with the matching cavity in the handle **700**. When the cavities are aligned, the stopper **762** is allowed to move from the cavity **766** to the cavity in the handle **700**, thus allowing the inner tube **720** to move axially and the anchor to be deployed.

Additionally, the drum **760** comprises a groove **768**. A spring-loaded sliding pin **770** (see FIG. **14**) may be coupled to the lever **706**. The lever **706** can only be moved when the drum **760** and switch **708** are rotated so that groove **768** is aligned with the pin **770**. Thus, both the stopper **764** and the pin **770** prevent the anchor from being deployed unless the switch **708** is in the correct position.

Those of skill in the art will appreciate other mechanisms that could be used for deploying a deployable anchor and providing safety mechanisms to prevent premature deployment.

Example Using a Piercing Anchor and a Suture Capturing Anchor

The above-described anchors may be used in a surgical procedure for attaching soft tissue to bone. One example of such a procedure is depicted in FIGS. **16**A through **16**F. In FIG. **16**A, the piercing anchor **800** attached to an anchor inserter **802** as described above is pierced through soft tissue **804** that has become detached from underlying bone **806**. In FIG. **16**B, the anchor inserter **802** is moved laterally relative to the bone **806** so as to stretch the soft tissue **804** laterally relative to the bone **806**. Once the soft tissue **804** has been stretched to the desired position, the anchor **800** is inserted into the bone **806** and the anchor **800** is deployed as described above and the inserter **802** is detached from the anchor **800**, leaving a suture **808** attached to the anchor **800** and extending through the soft tissue **804**. The anchor **800** may be inserted into bone **806** by tapping on the inserter **802** with a hammer or by any other suitable means of applying axial force. FIG. **16**C depicts the deployed anchor **800** with attached suture **808**. The suture **808** will extend into the inserter **802**.

Next, as depicted in FIG. **16**D, a suture capturing anchor **810** is inserted into the bone **806** using the inserter **812** as described above. In FIG. **16**E, the inserter **812** is then retracted to expose the suture capturing mechanism. The suture **808** is then passed over the soft tissue **804** and laterally moved into the suture capturing mechanism and tensioned. Finally, as depicted in FIG. **16**F, the suture capturing mechanism is deployed to capture the suture **808**, the anchor inserter **812** is detached from the anchor **810**, and the suture **808** is cut to detach it from the suture inserter **802**. The result is a length of suture **808** between the bone anchors **808** and **810** that presses the soft tissue **804** against the bone **806**. Multiple anchors and sutures may be used to produce geometries such as depicted in FIGS. **2** and **3** and variations thereof.

It will be appreciated that there are numerous stitches, suture threading patterns, and anchor patterns that may be used to secure soft tissue to bone by the methods and devices described herein. These variations as well as variations in the design of the above described anchor devices and inserter devices are within the scope of the present disclosure.

Methods of Attaching Soft Tissue to Bone

Various embodiments include methods for attaching soft tissue to bone. In some embodiments, the methods include using the bone anchors described above. In one embodiment, a bone anchor is inserted into the bone and then a length of suture is passed over the soft tissue and secured to the anchor after inserting the anchor without tying any knots or without passing the suture through an aperture in the anchor. In some embodiments, the suture is secured to the anchor by laterally moving it into a securing mechanism. In one embodiment, securing the suture to the anchor includes clamping the suture between at least two surfaces on the anchor. In one embodiment, the anchor is not inserted further into the bone after securing the suture to it.

In another embodiment, a first anchor with a suture pre-attached is inserted through the soft tissue and into the bone. The suture may then be passed over the soft tissue and fixedly secured to a second bone anchor. In one embodiment, the first anchor is inserted by directly piercing the soft tissue and the bone. In one embodiment, lateral protrusion may be deployed on the first anchor to prevent the first anchor from being removed. In one embodiment, the suture may be coupled to the second bone anchor prior to insertion and then fixedly secured after insertion. In this context, "coupled" means that the suture is attached to the bone anchor but not fixedly secured, such that the suture can move to some extent relative to the bone anchor. In an alternative embodiment, the suture is not coupled to the second bone anchor during its insertion.

In another embodiment, a first portion of suture is inserted into the proximal surface of the soft tissue. A second portion of the suture (e.g., the portion proximal to the inserted portion) is then passed over the proximal surface of the soft tissue and fixedly secured to a bone anchor. In one embodiment, the procedure may be performed without passing the first portion of the suture back out of the proximal surface of the soft tissue. In one embodiment, this result is accomplished by the first portion of the suture being attached to an anchor that is inserted through the soft tissue and into bone.

One embodiment includes inserting a first anchor with a pre-coupled suture through soft tissue and into bone. The suture may then be passed over the soft tissue and fixedly secured to a second anchor. In one embodiment, the pre-coupled suture is fixedly secured to the first anchor prior to insertion. In an alternative embodiment, the pre-coupled suture can move relative to the first anchor prior to insertion and is fixedly secured after insertion.

In another embodiment, multiple lengths of suture are attached to multiple anchors. In one embodiment at least three anchors are inserted into bone. A first length of suture may be secured between a first and second anchor and a second length of suture may be secured between the first and a third anchor. In one embodiment, the first anchor is positioned beneath the soft tissue and the second and third anchors are positioned laterally to the soft tissue. In an alternative embodiment, the first anchor is positioned laterally to the soft tissue and the second and third anchors are positioned beneath the soft tissue. In some embodiments, the lengths of suture are fixedly secured to the anchor(s) positioned beneath the soft tissue prior to insertion of those anchor(s). In one embodiment, the different lengths of suture may be tensioned separately.

In various embodiments, prior to fixedly securing suture to a bone anchor, it can be tensioned. In one embodiment, tensioning is accomplished by manually pulling on the suture such as by a surgeon grasping the suture using an appropriate instrument and then pulling. In one embodiment, the suture may be pressed against the bone anchor to provide leverage for pulling. For example, the suture may be wrapped partly around a proximal portion of the anchor prior to pulling.

Although the invention has been described with reference to embodiments and examples, it should be understood that numerous and various modifications can be made without departing from the spirit of the invention. Accordingly, the invention is limited only by the following claims.

What is claimed is:

1. A method of attaching soft tissue to bone, comprising:

inserting a first anchor into bone, wherein after insertion, the first anchor is positioned underneath the soft tissue;

passing a first length of suture from said first anchor over the soft tissue;

inserting a distal member of a second anchor into bone at a position beyond an edge of the soft tissue, wherein the second anchor comprises said distal member and a proximal member;

after inserting the distal member of the second anchor, tensioning the first length of suture to compress an area of tissue to bone between the edge of the soft tissue and the first anchor; and

after tensioning the first length of suture, moving the proximal member of the second anchor distally towards the distal member of the second anchor, thereby fixedly securing the first length of suture at the second anchor position without tying any knots.

2. The method of claim **1**, wherein the first length of suture is attached to the first anchor prior to insertion of the first anchor into bone.

3. The method of claim **1**, comprising forming a hole in the bone into which the distal member of the second anchor is inserted.

4. The method of claim **1**, wherein the distal member of the second anchor comprises a first proximally facing surface.

5. The method of claim **4**, wherein the proximal member of the second anchor has a second distally facing surface facing toward said first surface.

6. The method of claim **5**, wherein said proximal member is configured to move relative to said distal member such that it can be positioned in a first configuration wherein said first and second surfaces are spaced apart and be positioned in a second configuration wherein said first and second surfaces are in close proximity.

7. The method of claim **1**, wherein the distal member of the second anchor is tapered.

8. The method of claim 1, wherein a proximal portion of the distal member of the second anchor comprises a suture gripping structure.

9. The method of claim 1, wherein a proximal end of the distal member of the second anchor comprises a hole opening into a central bore.

10. The method of claim 9, wherein sides of the central bore comprise threads.

11. The method of claim 1, wherein the proximal member of the second anchor is cylindrically shaped.

12. The method of claim 1, wherein a central bore extends through the proximal member of the second anchor.

13. The method of claim 12, wherein inserting the distal member of the second anchor and moving the proximal member of the second anchor distally toward the distal member comprises using an anchor inserter comprising a handle, a tube, and an inner member, wherein the inner member extends through the tube and the central bore in the proximal member of the second anchor and is removably coupled to the distal member of the second anchor.

14. The method of claim 13, wherein the inserter comprises an inner tube and an outer tube, wherein the inner tube extends through the outer tube, and wherein the inner member extends through the inner tube.

15. The method of claim 13, wherein the tube is movable longitudinally relative to the inner member.

16. The method of claim 1, comprising coupling the first length of suture to the second anchor prior to inserting the distal member of the second anchor into bone.

17. The method of claim 1, wherein the tensioning comprises manually pulling on the first length of suture.

18. The method of claim 1, comprising:

inserting a third anchor into bone, wherein after insertion, the third anchor is positioned underneath the soft tissue;

passing a second length of suture from said third anchor over the soft issue;

tensioning the second length of suture independently from the first length of suture; and

after tensioning the first and second lengths of suture, moving the proximal member of the second anchor distally towards the distal member of the second anchor, thereby fixedly securing both the first and second lengths of suture at the second anchor position without tying any knots.

19. A method of attaching soft tissue to bone, comprising:

inserting a first anchor into bone, wherein after insertion, the first anchor is positioned underneath the soft tissue;

passing a first length of suture from said first anchor over the soft tissue;

coupling the first length of suture to a second anchor, wherein the second anchor comprises a distal member and a proximal member, wherein said proximal member is cylindrically shaped and comprises a central bore extending therethrough;

after coupling the first length of suture to the second anchor, inserting the distal member of the second anchor into bone at a position beyond an edge of the soft tissue;

after inserting the distal member of the second anchor, tensioning the first length of suture to compress an area of tissue to bone between the edge of the soft tissue and the first anchor; and

after tensioning the first length of suture, moving the proximal member of the second anchor distally towards the distal member of the second anchor, thereby fixedly securing the first length of suture at the second anchor position without tying any knots, wherein inserting the distal member of the second anchor and moving the proximal member of the second anchor distally toward the distal member comprises using an anchor inserter comprising a handle, a tube, and an inner member, wherein the inner member extends through the tube and the central bore in the proximal member of the second anchor and is removably coupled to the distal member of the second anchor.

* * * * *

EXHIBIT 3

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(12) **United States Patent**
Green et al.

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(45) **Date of Patent: *Feb. 7, 2012**

(54) **SYSTEM AND METHOD FOR ATTACHING SOFT TISSUE TO BONE**

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This patent is subject to a terminal disclaimer.

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(60) Provisional application No. 60/576,477, filed on Jun. 2, 2004, provisional application No. 60/610,924, filed on Sep. 17, 2004, provisional application No. 60/634,174, filed on Dec. 7, 2004.

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A61B 17/04 (2006.01)

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(58) **Field of Classification Search** 606/72, 606/75, 78, 219, 224, 232, 300–331
See application file for complete search history.

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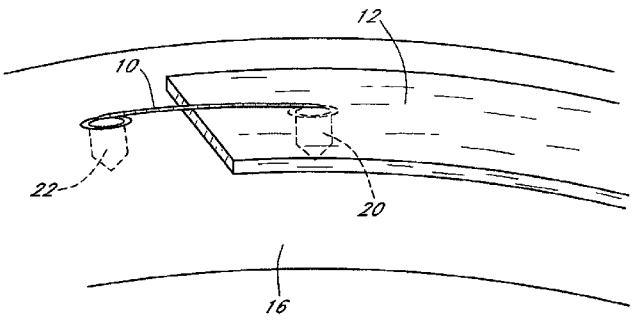
(57) **ABSTRACT**

Disclosed herein are methods and devices for securing soft tissue to a rigid material such as bone. A bone anchor is described that comprises a base and a top such that suture material may be compressed between surfaces on the base and top to secure the suture to the anchor. Also described is an inserter that can be used to insert the bone anchor into bone and move the anchor top relative to the anchor base to clamp suture material there between. Also described is a soft-tissue and bone piercing anchor and associated inserter. Methods are described that allow use of the bone anchors to provide multiple lengths of suture material to compress a large area of soft tissue against bone.

17 Claims, 24 Drawing Sheets



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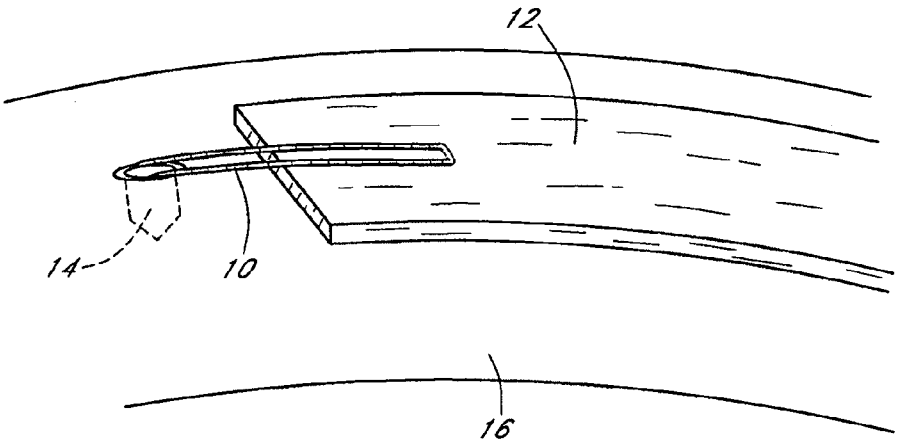

FIG. 1

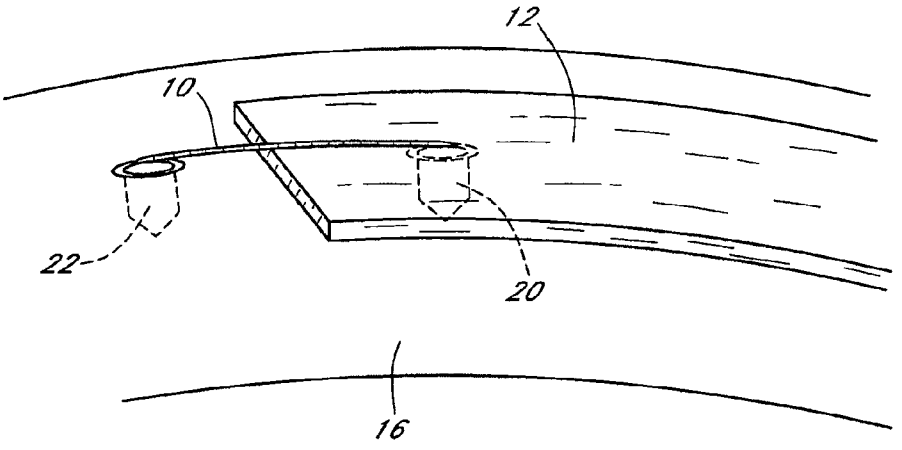

FIG. 2

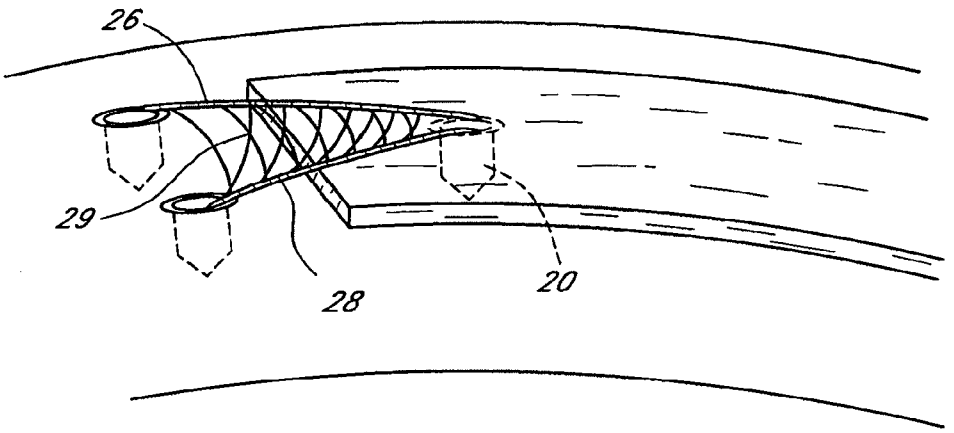

FIG. 3A

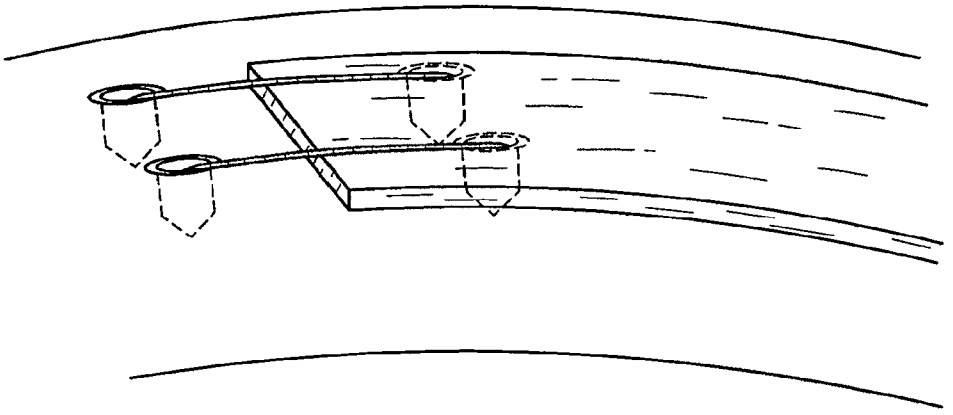

FIG. 3B

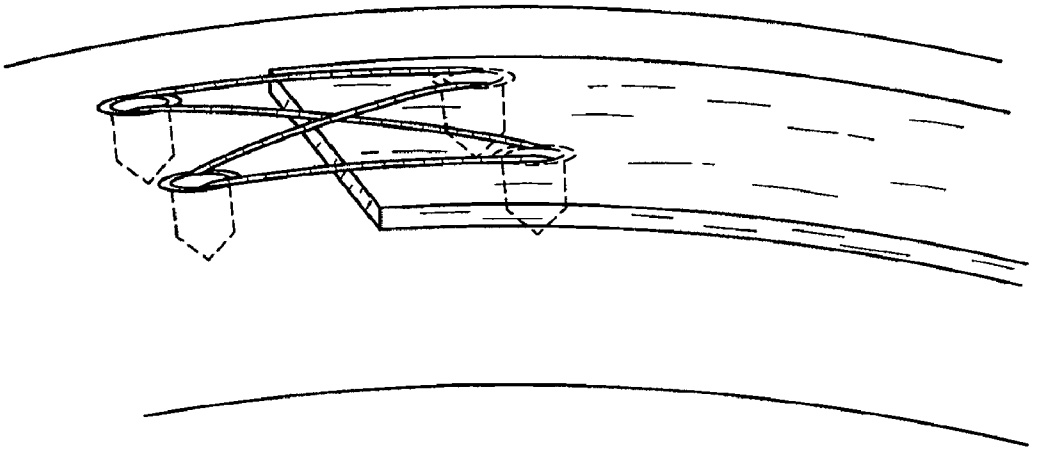

FIG. 3C

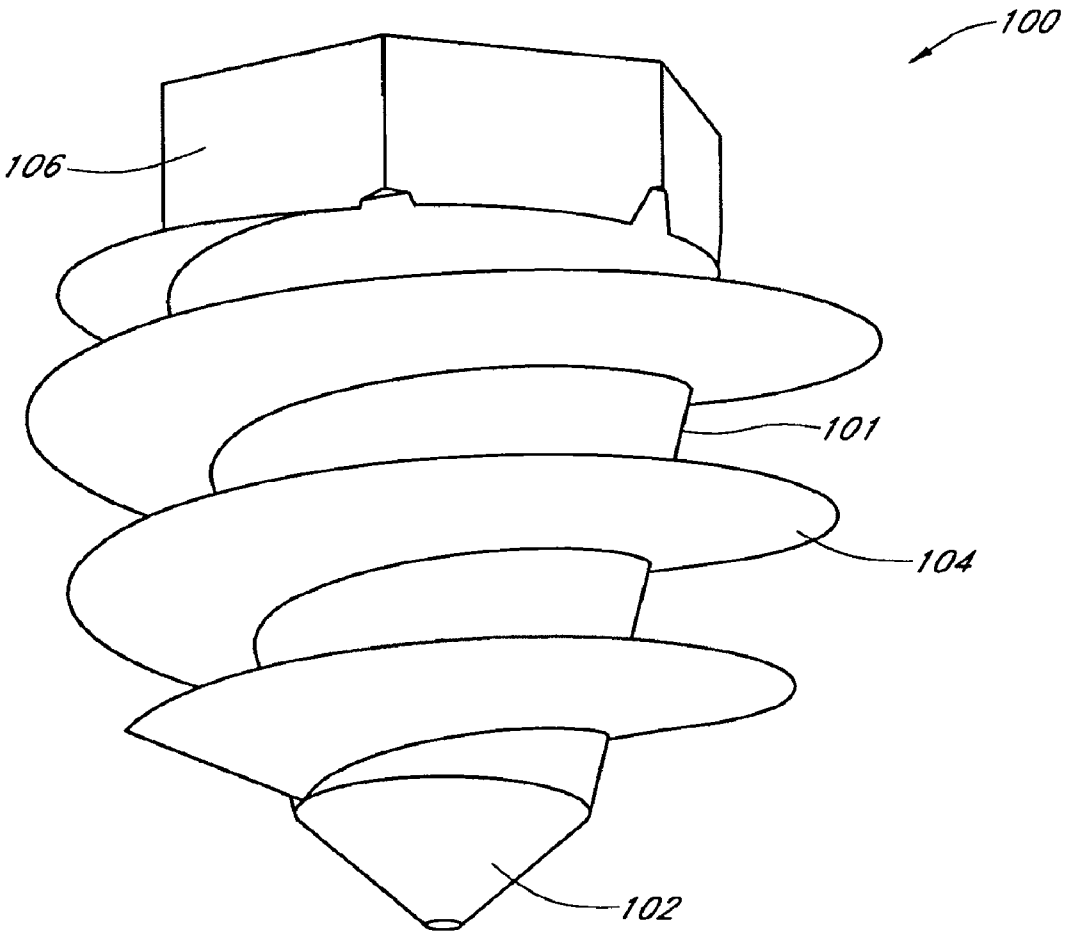

FIG. 4A

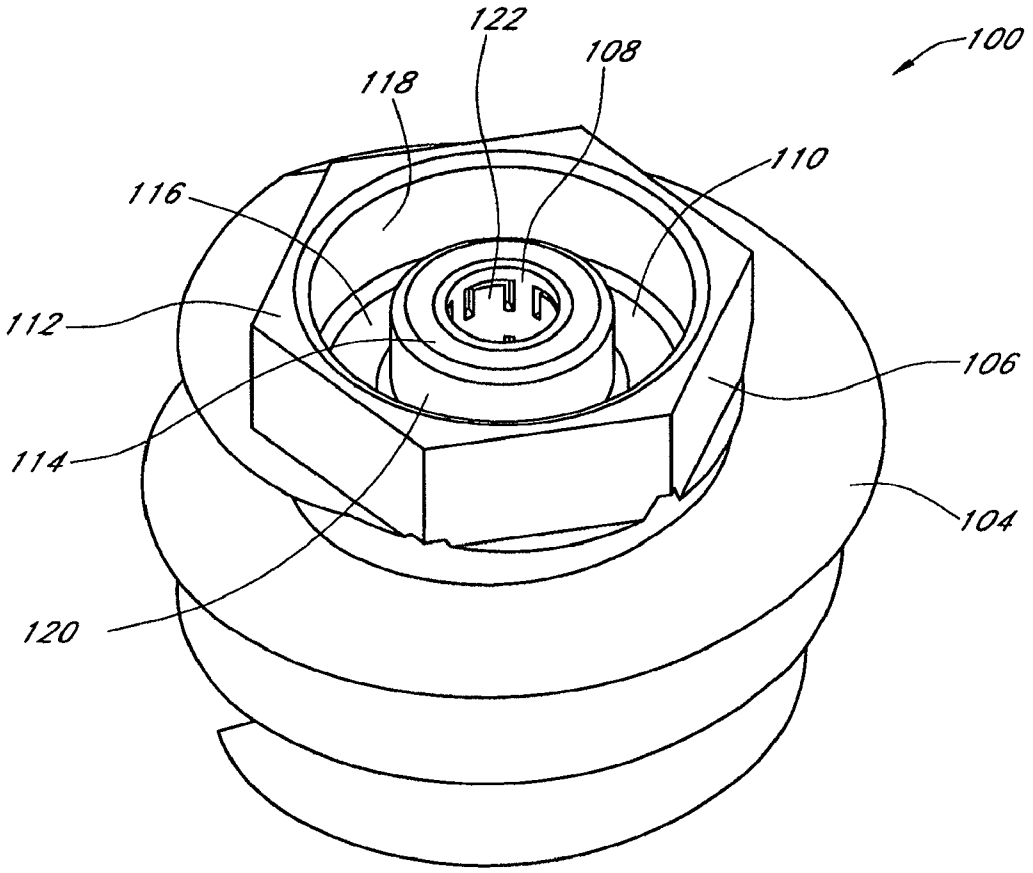

FIG. 4B

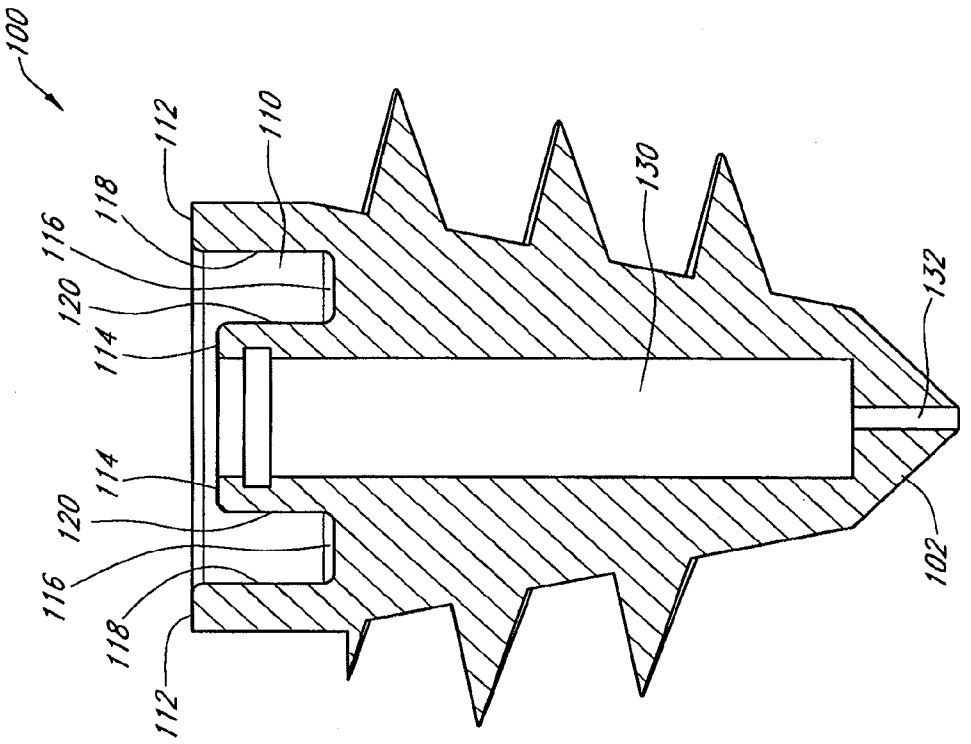
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FIG. 4D

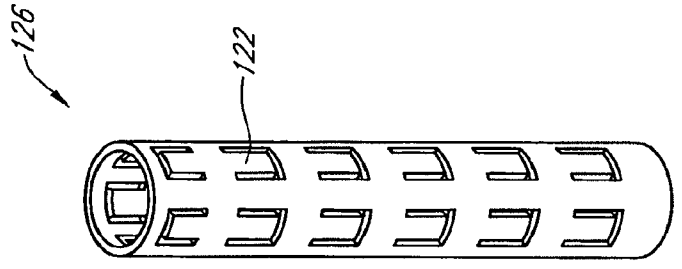
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FIG. 4C

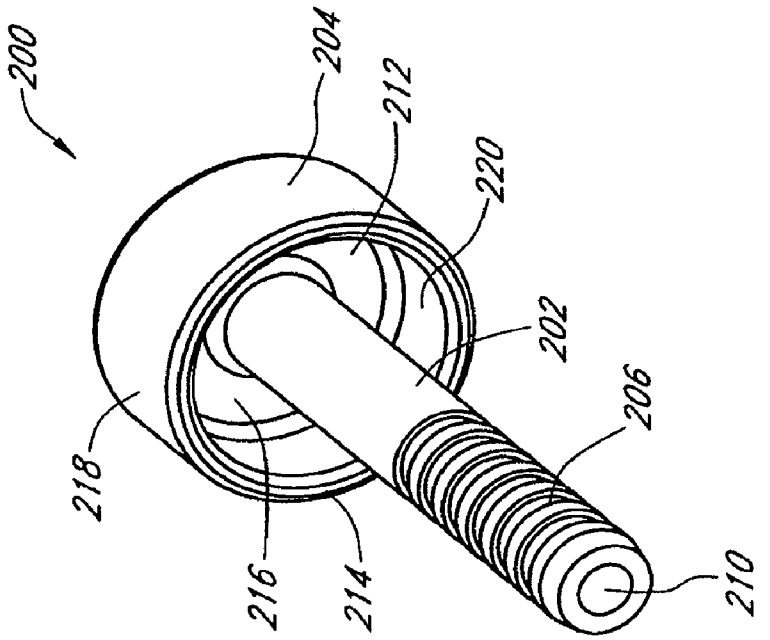

FIG. 5B

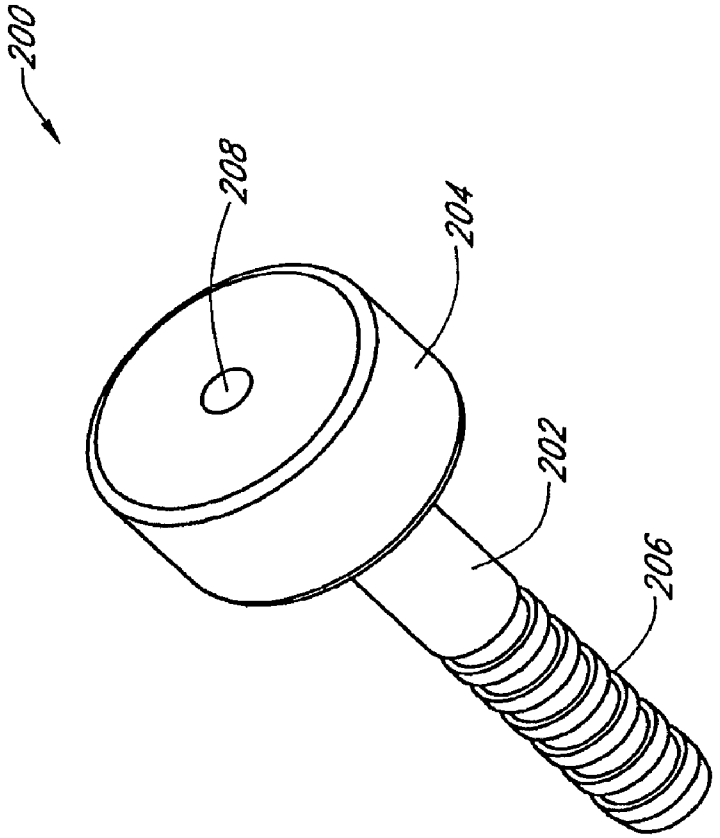

FIG. 5A

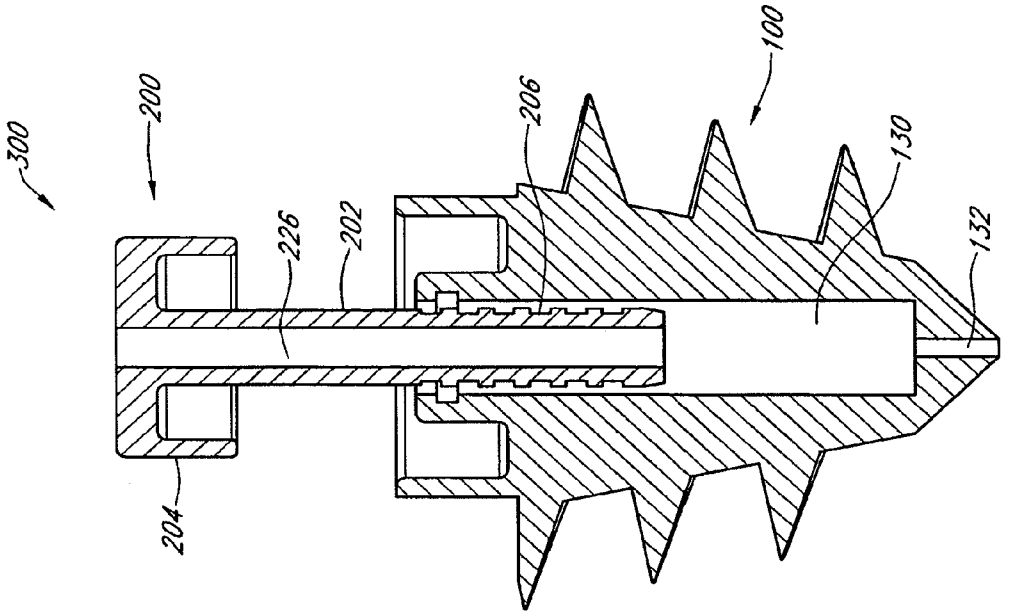
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FIG. 6A

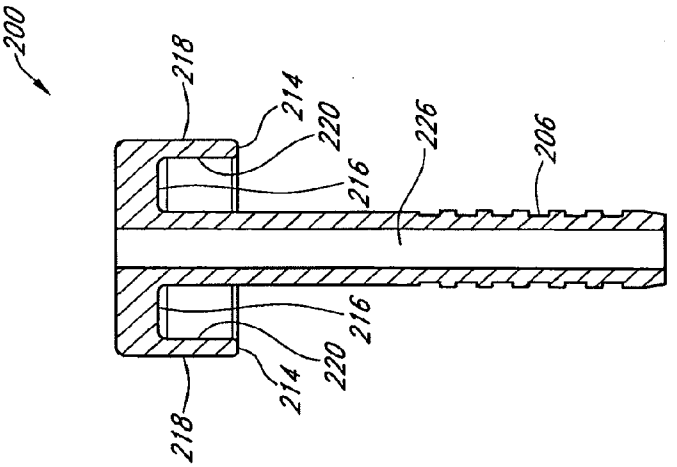
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FIG. 5C

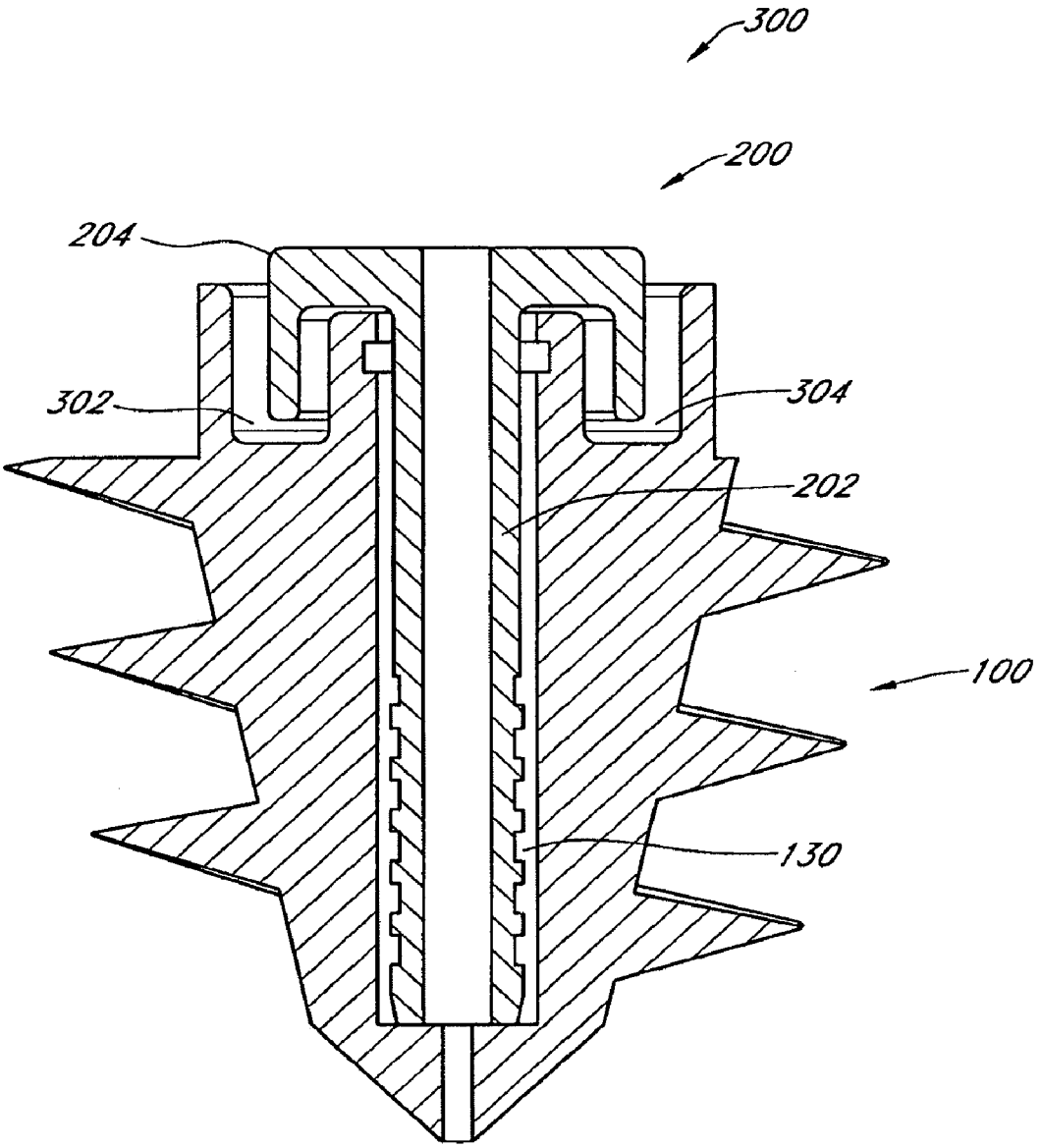

FIG. 6B

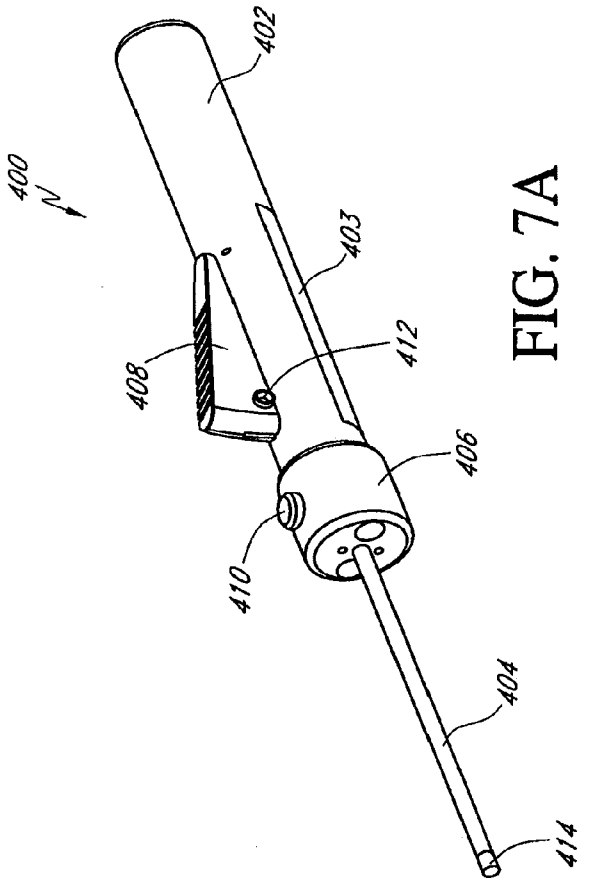
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FIG. 7A

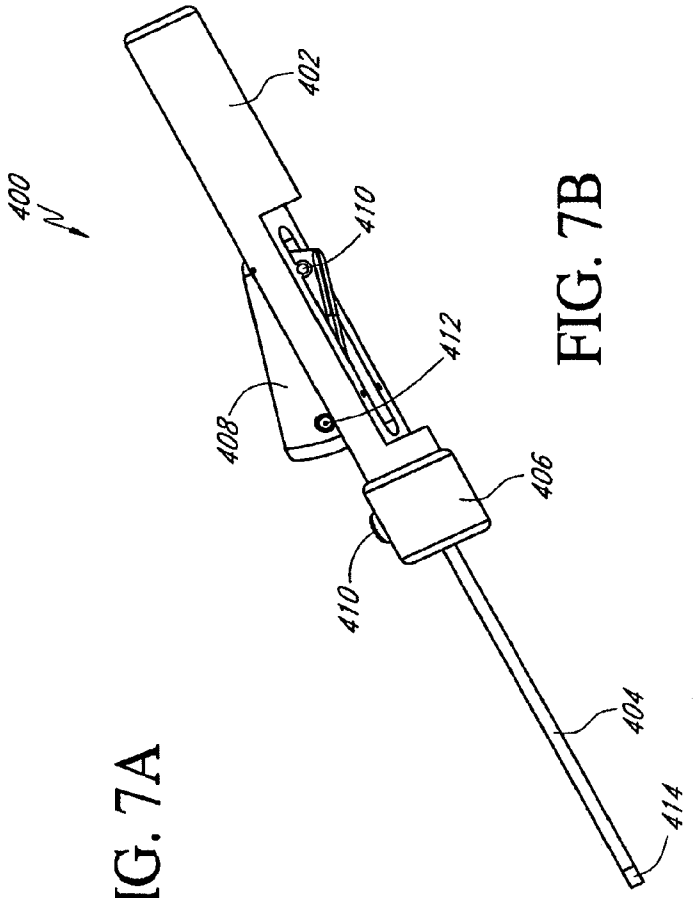
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FIG. 7B

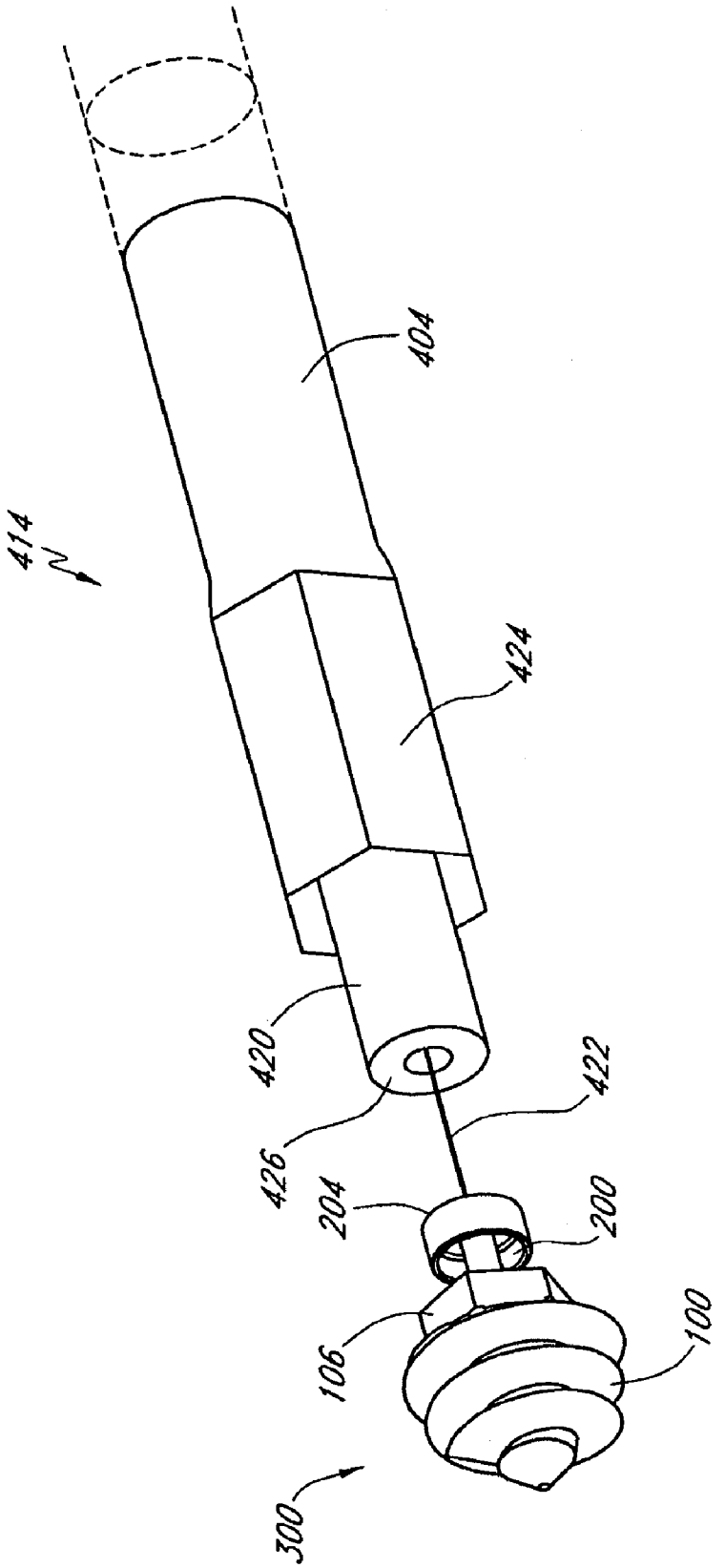

FIG. 8

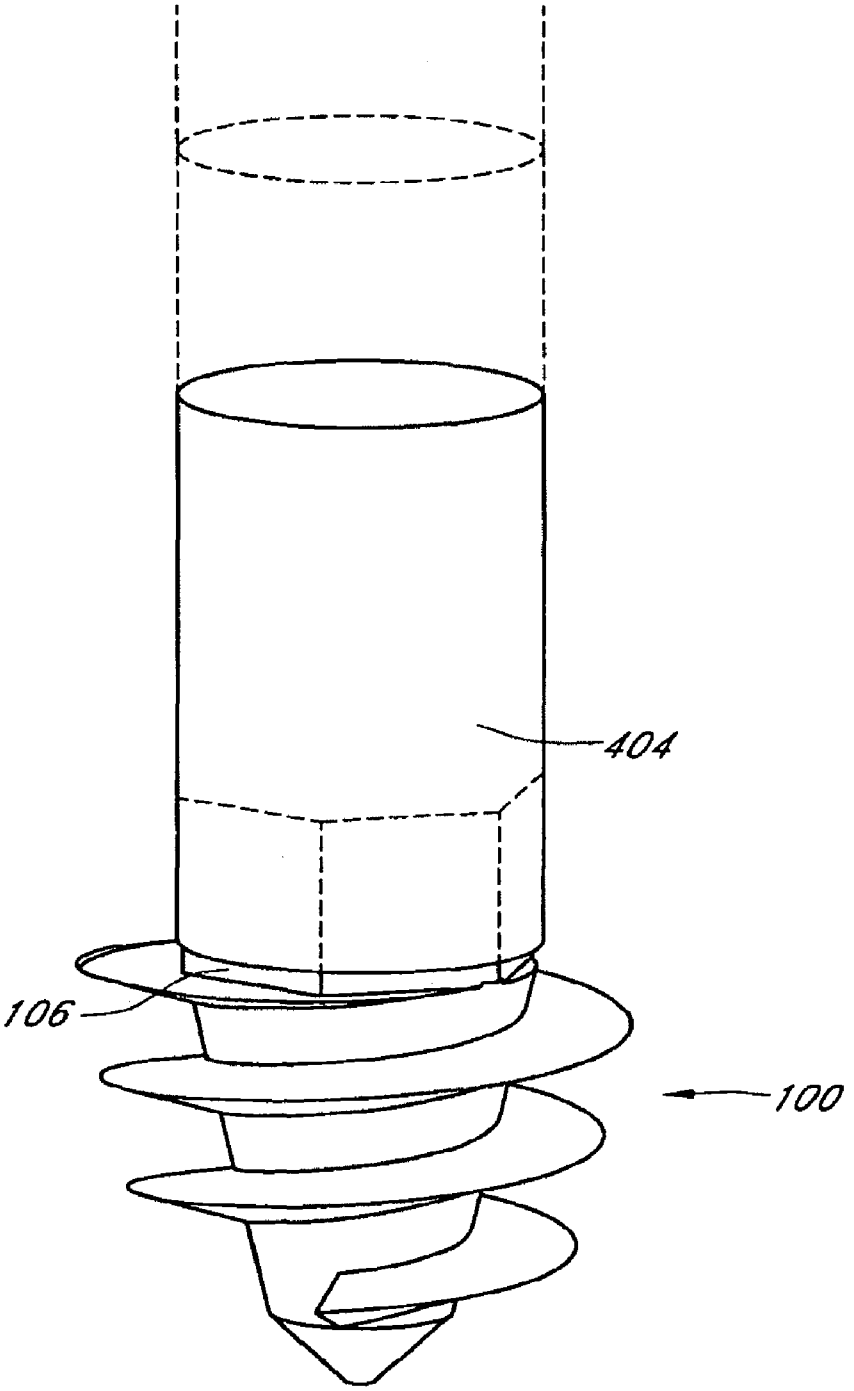

FIG. 9A

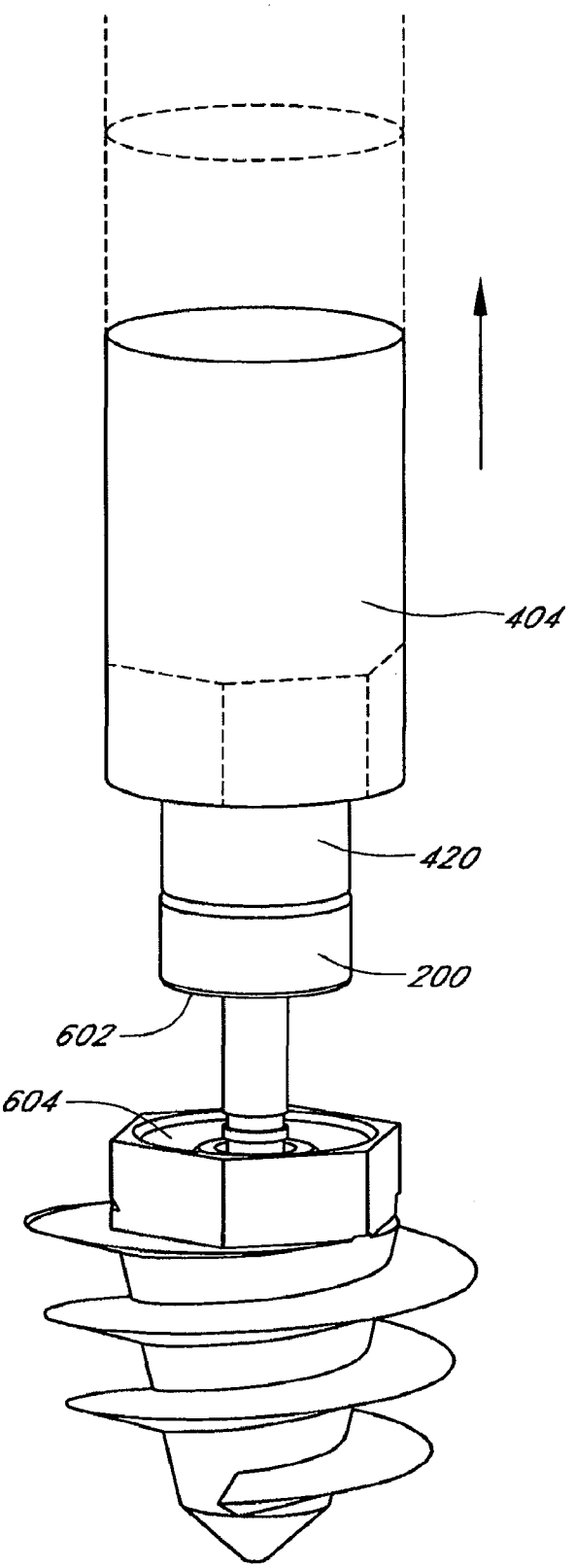

FIG. 9B

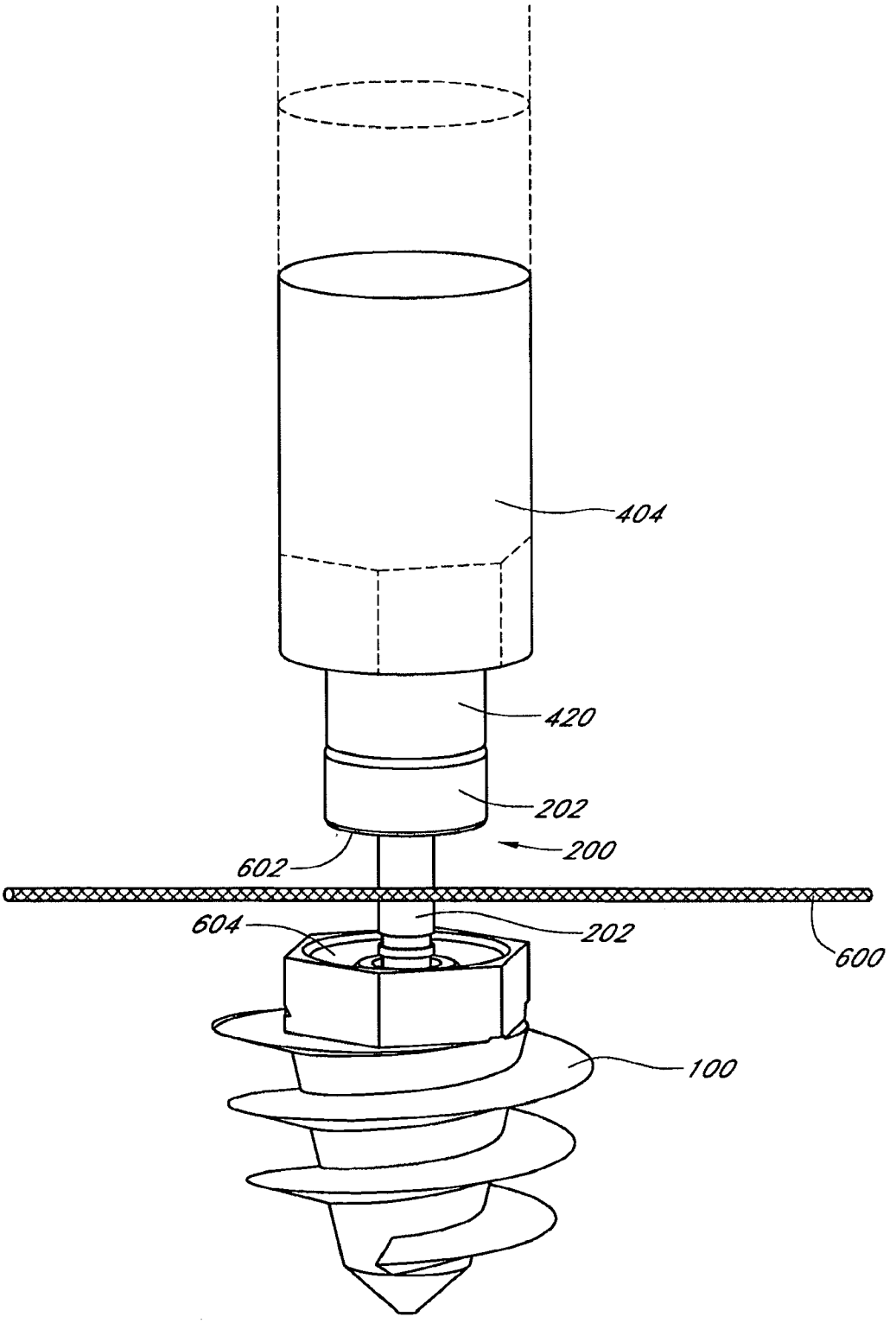

FIG. 9C

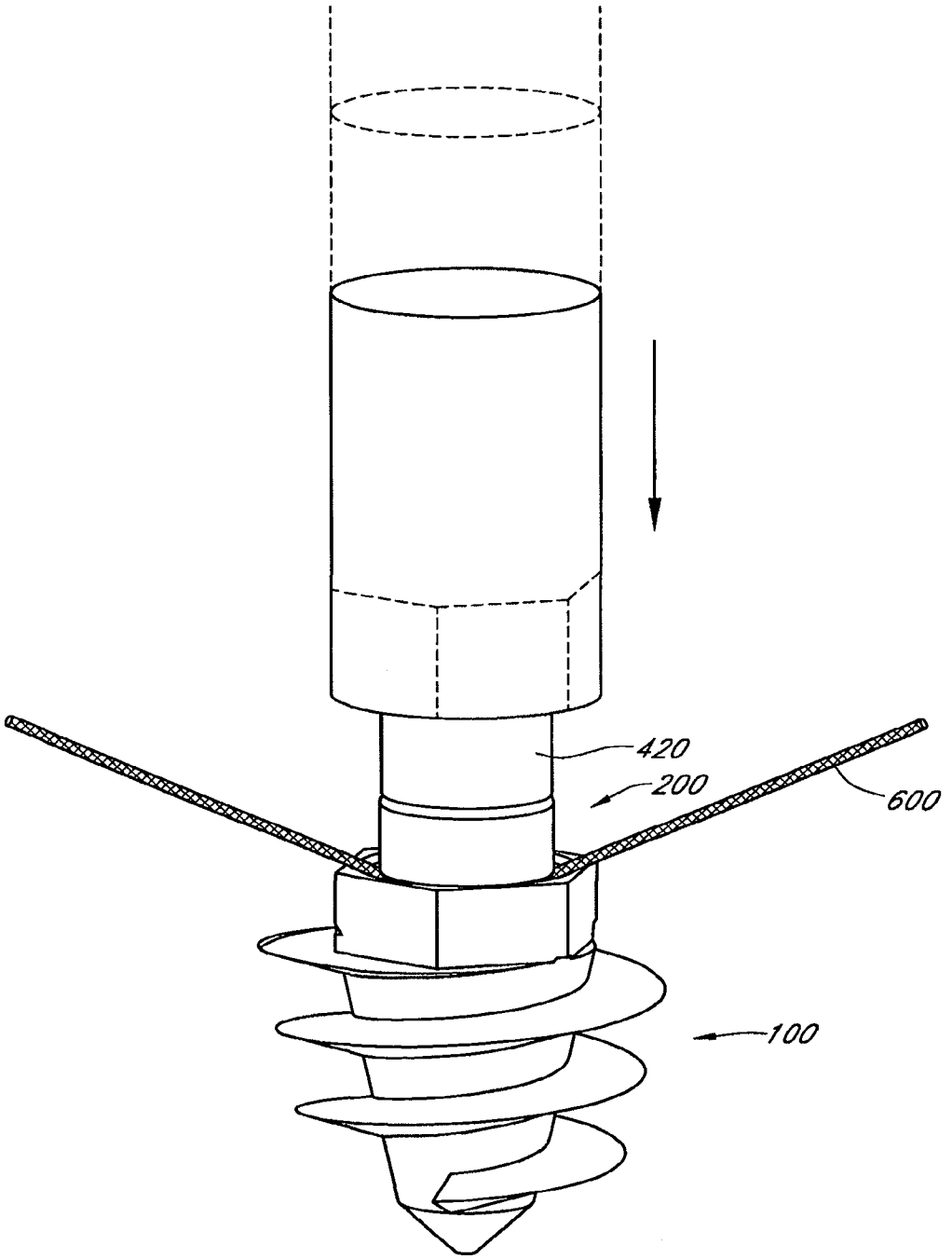

FIG. 9D

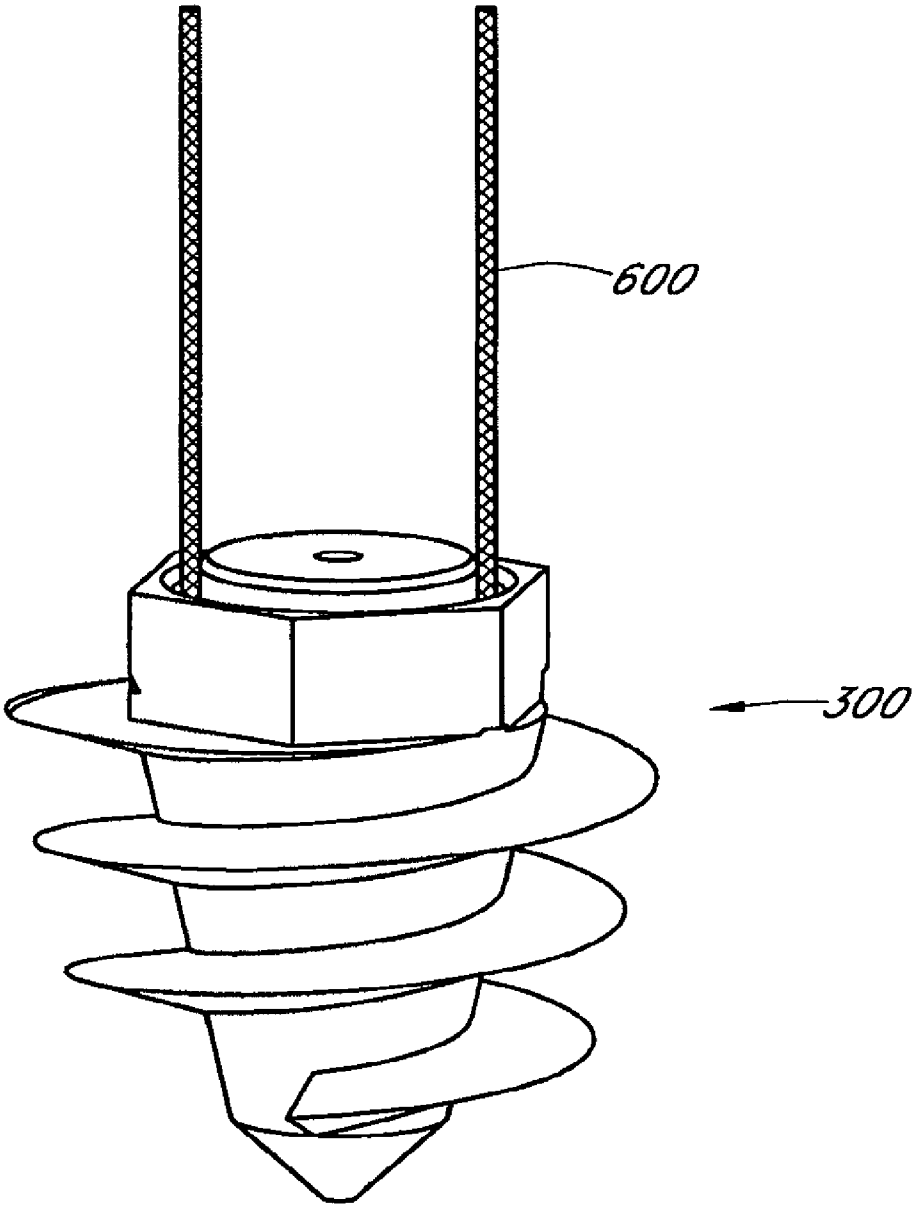

FIG. 9E

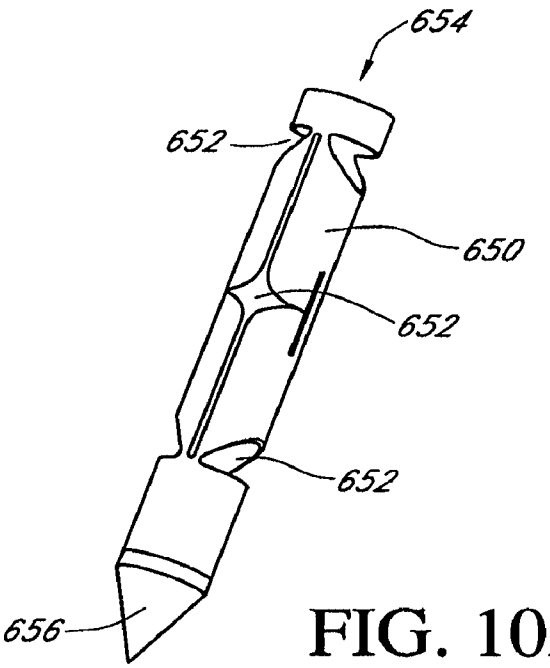

FIG. 10A

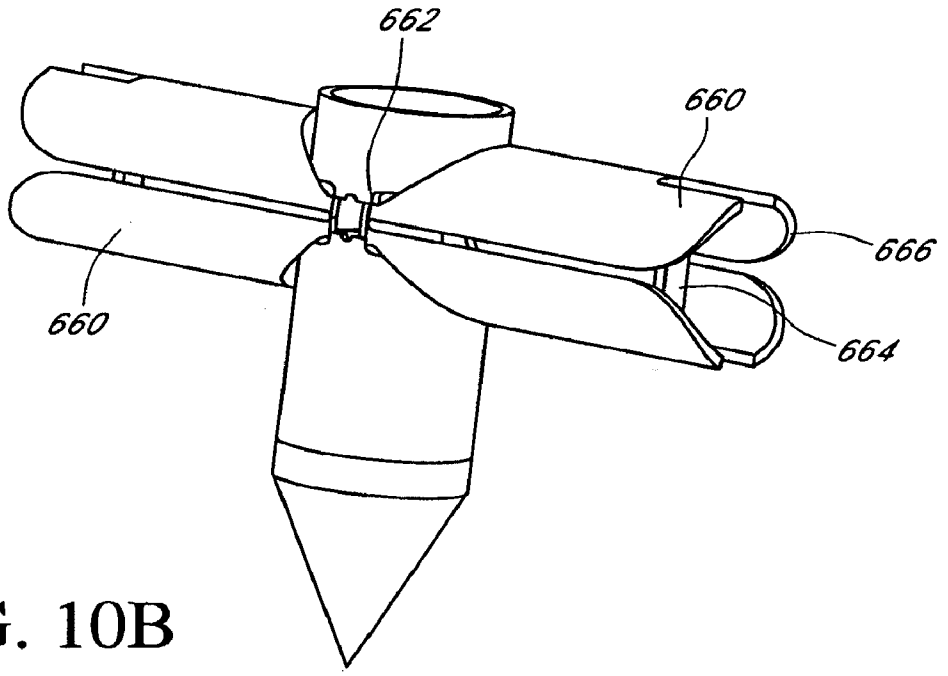

FIG. 10B

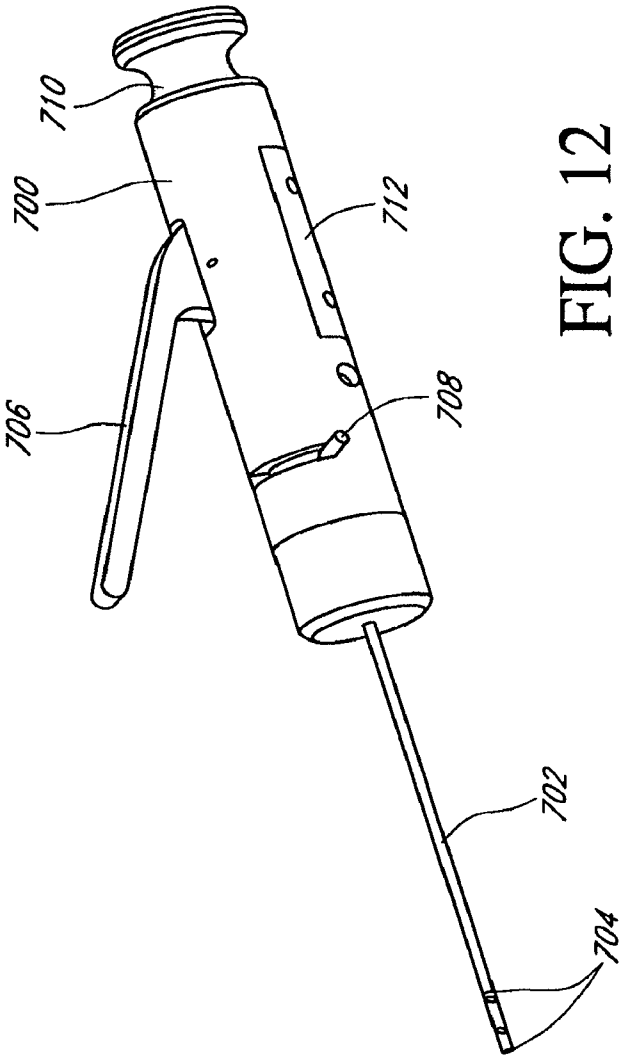

FIG. 12

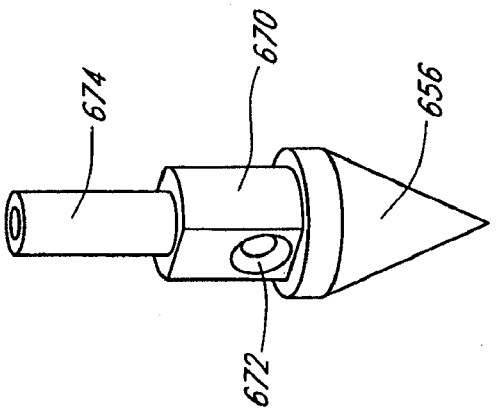

FIG. 11

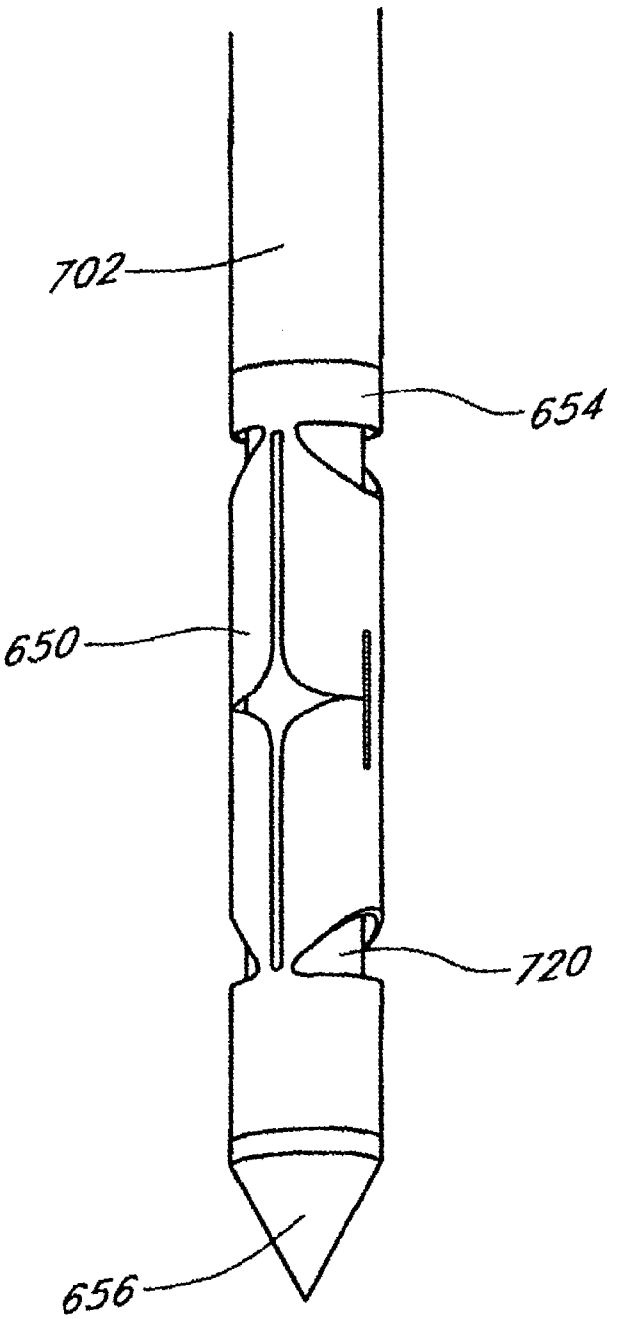

FIG. 13

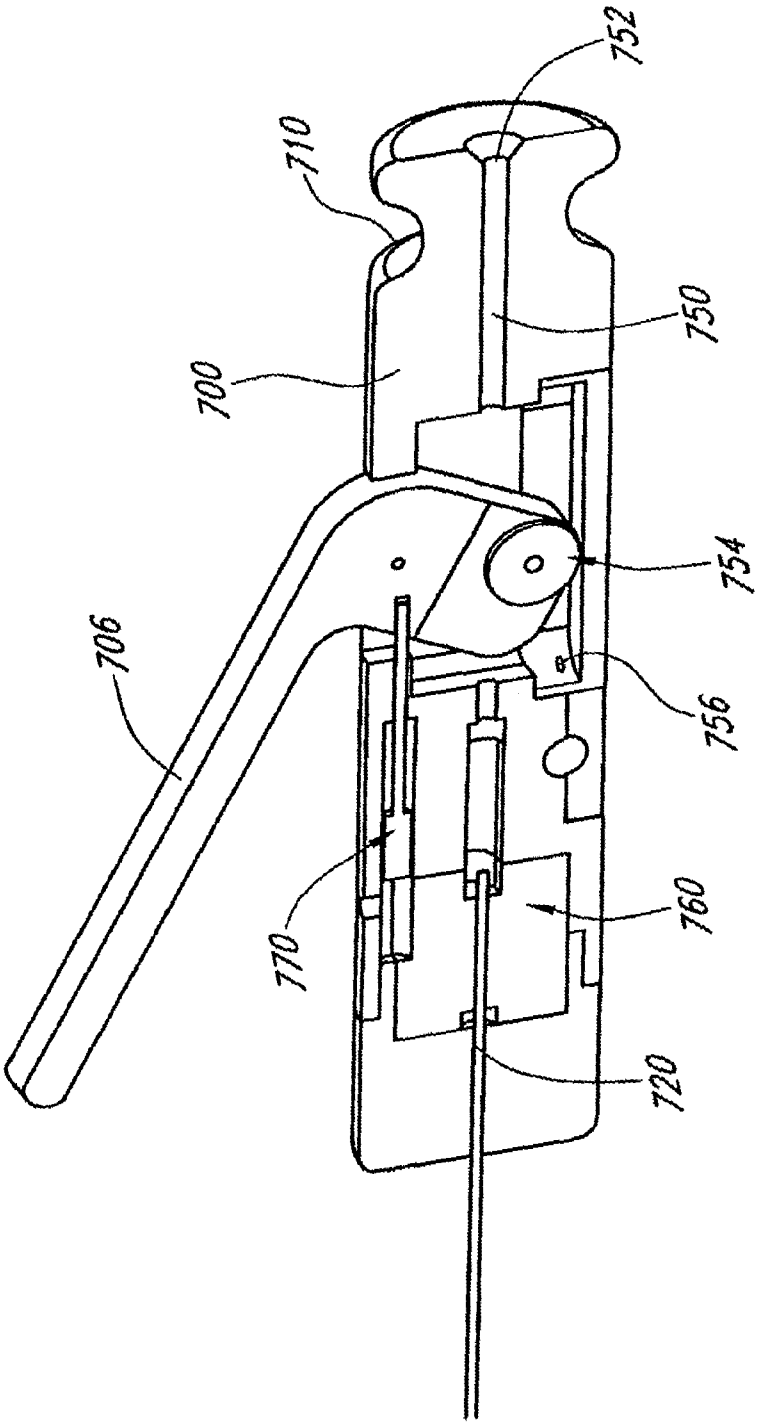

FIG. 14

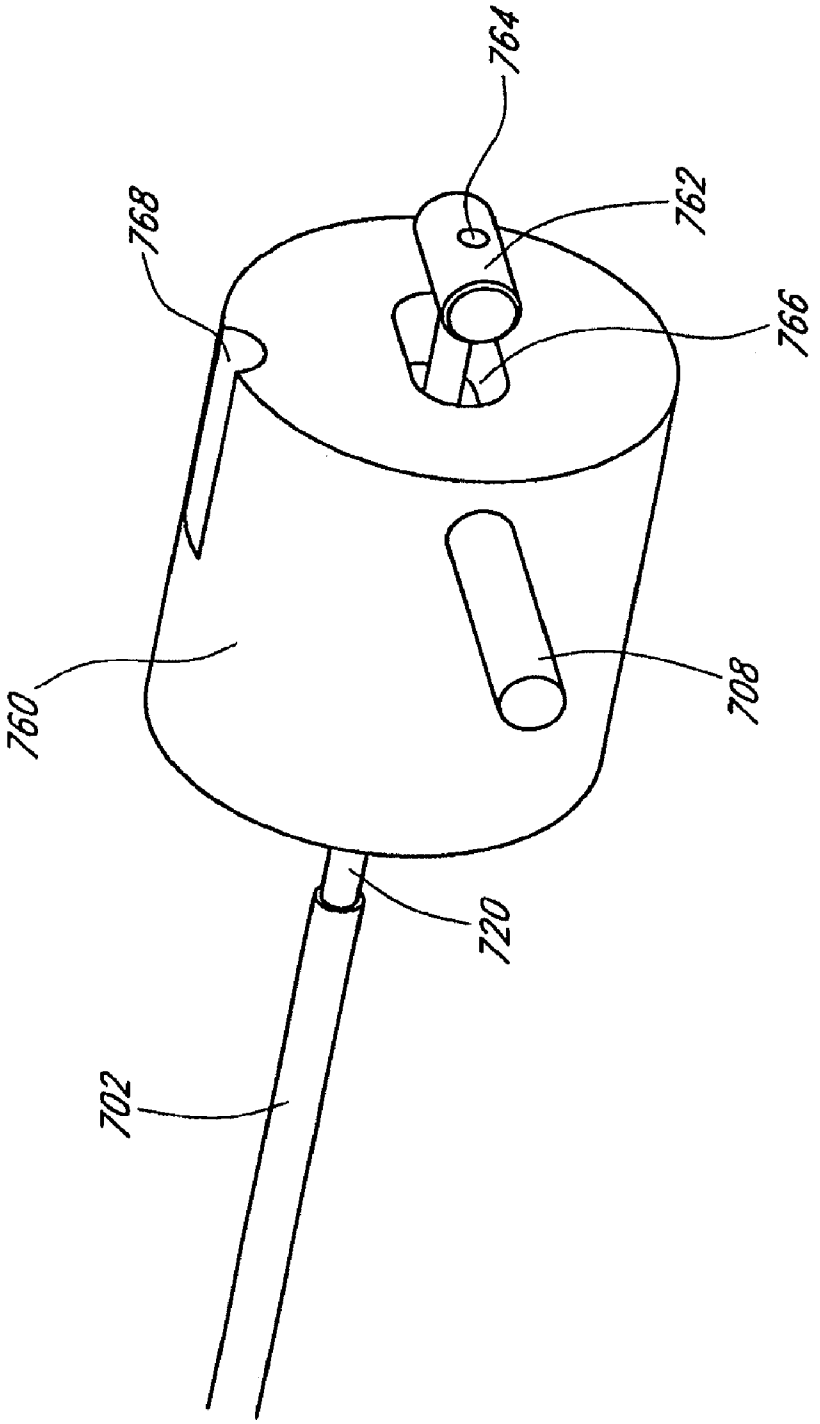

FIG. 15

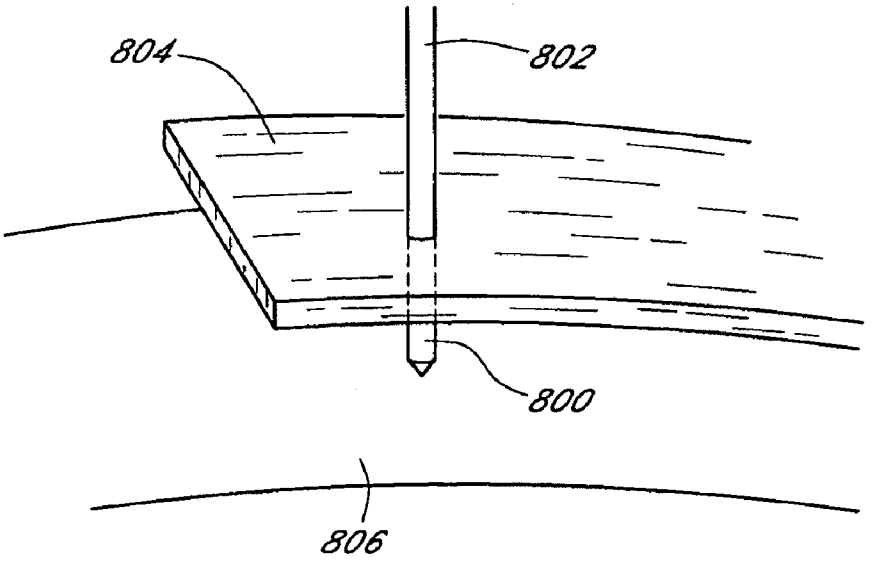

FIG. 16A

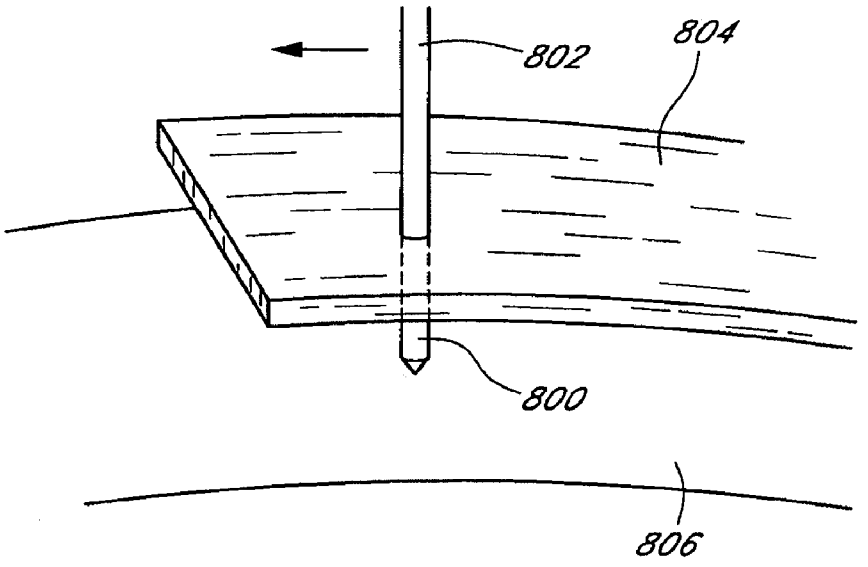

FIG. 16B

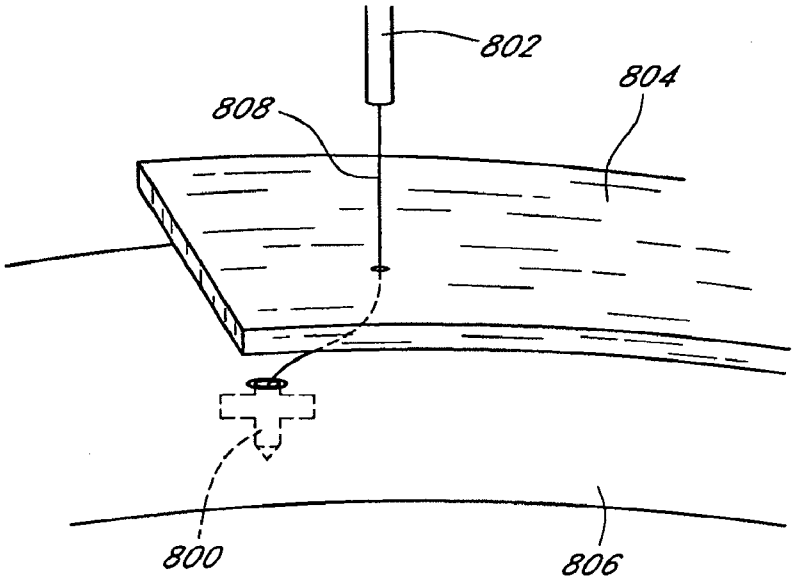

FIG. 16C

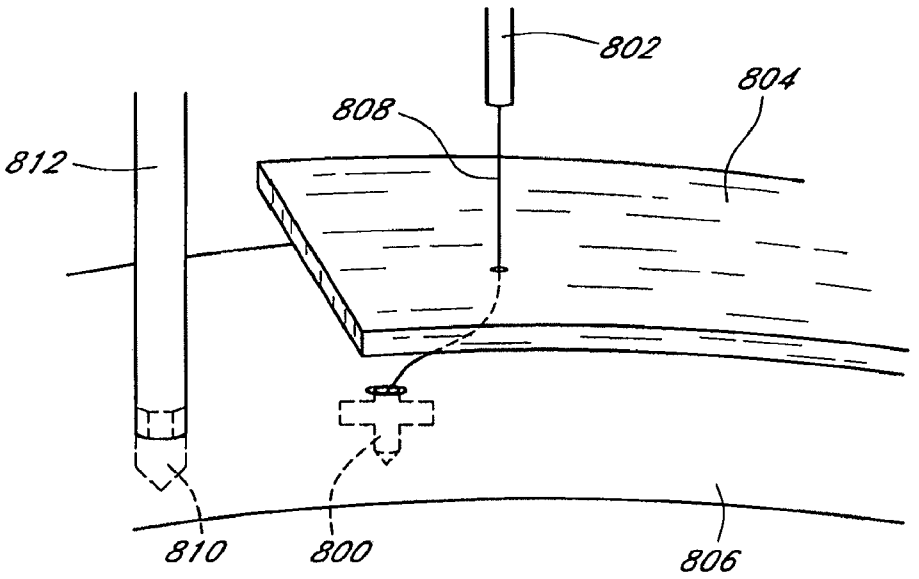

FIG. 16D

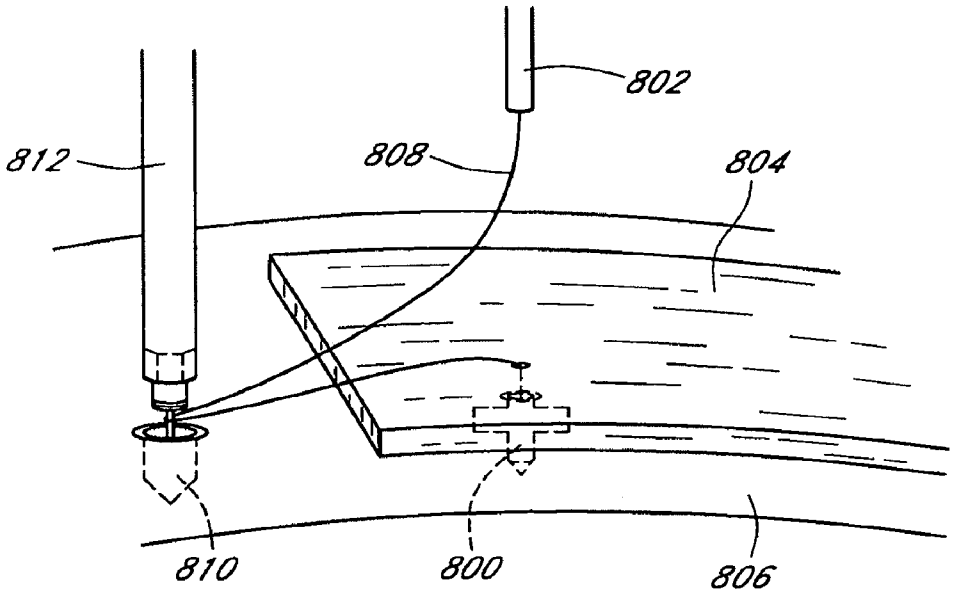

FIG. 16E

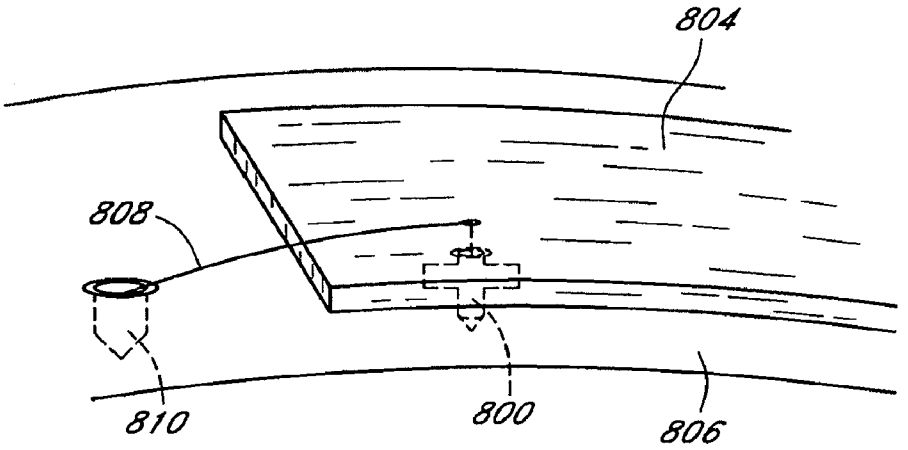

FIG. 16F

SYSTEM AND METHOD FOR ATTACHING SOFT TISSUE TO BONE

RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 12/549,105, filed Aug. 27, 2009, which is a divisional of U.S. application Ser. No. 11/143,007, now U.S. Pat. No. 7,585,311, filed Jun. 1, 2005, which claims priority to U.S. Provisional Application Nos. 60/576,477, filed on Jun. 2, 2004; 60/610,924, filed on Sep. 17, 2004; and 60/634,174, filed on Dec. 7, 2004; all of which are incorporated herein by reference in their entirety.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to medical devices and procedures. More particularly, the present invention relates to devices and methods for securing soft tissue to a rigid material such as bone.

2. Description of the Related Art

There are several medical procedures where a surgeon needs to attach soft tissue such as tendons or other soft connective tissue to bone. One common example is a torn rotator cuff, where the supraspinatus tendon has separated from the humerus causing pain and loss of ability to elevate and externally rotate the arm. To repair a torn rotator cuff, typically a surgical procedure is used to suture the torn tendon to the bone using a variety of methods. Some procedures utilize large incisions and involve complete detachment of the deltoid muscle from the acromion. Small diameter holes are made in the bone for passing suture material through the bone to secure the tendon. Such large incision procedures are traumatic, causing prolonged pain and recovery time. Other procedures make small incisions and use arthroscopic techniques to attach sutures using either small diameter holes or a bone anchor. However, it is difficult to manipulate sutures within the surgical site using arthroscopic techniques. In addition, when knot tying is used to secure the suture to a bone anchor, it is difficult to properly adjust the tension of the suture while tightening the knot. Similarly, when the suture is attached to a bone anchor prior to insertion of the anchor into the bone, it is difficult to judge the appropriate point of attachment so that the suture will be properly tensioned upon insertion of the bone anchor into the bone. Thus, there is a need for methods and devices that allow easy arthroscopic attachment of a suture to a bone anchor after the anchor is inserted into the bone without the use of knot tying.

SUMMARY OF THE INVENTION

The present invention is particularly suited for use in arthroscopic procedures, including but not limited to rotator cuff surgery. More broadly, it can be used in any procedure in which it is desired to fix a suture to a solid object without tying of knots, including not only arthroscopic procedures, but also open surgery, and can be used for such diverse purposes as bladder neck suspension, tendon and ligament affixation or repair, prosthetic attachment, and rotator cuff repair.

In one embodiment, the invention includes an anchor for securing a suture to bone, including an anchor base adapted to be securely fixed into the bone and a suture securing mechanism coupled to the anchor base and positioned proximally relative to the anchor base, the mechanism adapted to receive and secure a suture moved laterally into the

In another embodiment, the invention includes an anchor for securing a suture to bone, including an anchor base adapted to be securely fixed into the bone, a first surface coupled to the anchor base and positioned proximally relative to the anchor base, and a second surface coupled to the anchor base and positioned proximally relative to the anchor base, wherein the first and second surfaces are adapted to be relatively positioned in at least two configurations, one of the configurations such that a gap is present between the first and second surfaces so that the suture can be positioned between the first and second surfaces by moving the suture laterally into the gap, and the other of the configurations such that the first and second surfaces are in close proximity so that the suture can be securely clamped between the first and second surfaces.

In another embodiment, the invention includes a method of attaching soft tissue to bone, including passing a length of suture over the soft tissue, inserting an anchor into the bone, and securing the length of suture to the anchor after the inserting without passing an end of the length of suture through any aperture in the anchor and without tying any knots.

In another embodiment, the invention includes a method of attaching soft tissue to bone, including inserting a first anchor through the soft tissue, wherein the first anchor comprises a length of suture fixedly secured to the first anchor prior to insertion, inserting the first anchor into the bone, passing the length of suture over the soft tissue, and fixedly securing, after the passing, the length of suture to a second anchor.

In another embodiment, the invention includes a method of attaching soft tissue to bone, the soft tissue comprising a first surface adjacent to the bone's surface and a second surface opposite the first surface, the method including inserting a first portion of a length of suture into the second surface of the soft tissue, passing a second portion of the length of suture over the second surface of the soft tissue, inserting a first anchor with no suture coupled thereto into the bone, and fixedly securing the length of suture to the inserted first anchor, with the proviso that no part of the first portion of the length of suture is passed out of the second surface of the soft tissue.

In another embodiment, the invention includes a method of attaching soft tissue to bone, including inserting a first anchor with a length of suture pre-coupled thereto through the soft tissue, inserting the first anchor into the bone, inserting a second anchor with no suture coupled thereto into bone, passing the length of suture over the soft tissue, and fixedly securing the length of suture to the inserted second anchor.

In another embodiment, the invention includes a method of attaching soft tissue to bone, the method including inserting a first, second, and third anchor into the bone, fixedly securing a first length of suture over the soft tissue to the first and second anchors, and fixedly securing a second length of suture over the soft tissue to the first and third anchors.

In another embodiment, the invention includes an anchor for securing a suture to bone, the anchor including an anchor base adapted to be securely fixed into the bone, the anchor base comprising a first proximal surface and an anchor top, the anchor top comprising a distal member coupled to the anchor base and a first proximal member comprising a first distal surface, wherein the anchor top is adapted to couple to the anchor base in at least two configurations, one of the configurations such that the first distal surface is above the bone's surface when the anchor base is securely fixed into the bone, such that a suture can be freely passed between the first proximal and first distal surfaces above the bone's surface, and the other of the configurations such that the first distal

surface is in close proximity to the first proximal surface, such that a suture can be securely clamped between the first proximal and first distal surfaces.

In another embodiment, the invention includes an anchor for securing a suture to bone, the anchor including a substantially hollow cylinder comprising an open end and comprising a portion of its walls cut in such a manner so as to allow the cylinder to deform under stress and form lateral protrusions, a substantially pointed tip coupled to the cylinder opposite the open end, wherein the pointed tip is adapted to pierce the bone, and a suture receiver coupled to the pointed tip and positioned within the substantially hollow cylinder so that a suture may be attached to the suture receiver and extend through the cylinder and out of the open end.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** depicts attaching soft tissue to bone using a single bone anchor and a stitch.

FIG. **2** depicts attaching soft tissue to bone using a two bone anchors with a suture stretched there between.

FIGS. **3**A-**3**C depict various geometries of bone anchors and suture patterns for attaching soft tissue to bone.

FIGS. **4**A-**4**D depicts the base of a two-part suture anchor that can be inserted into bone.

FIGS. **5**A-**5**C depicts the top of a two-part suture anchor.

FIGS. **6**A and **6**B depict the suture anchor top of FIGS. **5**A-**5**C inserted into the suture anchor bottom of FIGS. **4**A-**4**D.

FIGS. **7**A and **7**B depict a suture anchor inserter.

FIG. **8** depicts components on a suture anchor inserter for attaching to bone and manipulating a suture anchor.

FIGS. **9**A-**9**E depicts manipulation of a suture anchor using a suture anchor inserter to insert the suture anchor into bone and attach suture material to the suture anchor.

FIGS. **10**A and **10**B depict a piercing bone anchor in an un-deployed (FIG. **10**A) and deployed (FIG. **10**B) state.

FIG. **11** depicts a piercing bone anchor tip.

FIG. **12** depicts an anchor inserter for inserting a piercing bone anchor.

FIG. **13** depicts the interface between a piercing bone anchor and an anchor inserter.

FIG. **14** is a cut-away view of a bone anchor inserter.

FIG. **15** depicts a safety switch mechanism for a bone anchor inserter.

FIGS. **16**A-**16**F depict a method for attaching soft-tissue to bone using a piercing bone anchor and a suture capturing anchor.

DETAILED DESCRIPTION OF THE CERTAIN EMBODIMENTS

In various embodiments, soft tissue may be attached to bone utilizing one or more bone anchors with suture attached thereto. As used herein, "suture" refers to any flexible structure that can be stretched between two or more anchors and includes, without limitation, traditional suture material, single or multiple stranded threads, or a mesh structure. In some embodiments, suture is passed over the top of the soft tissue so that the suture can press the soft tissue against the bone. In one embodiment, a length of suture is attached to a single bone anchor. One non-limiting example, depicted in FIG. **1**, includes stitching the suture **10** to the soft tissue **12**, such as by an incline mattress stitch, and then securing the suture **10** to the single bone anchor **14** that is inserted into the bone **16**. However, in other embodiments, a length of suture is attached to multiple bone anchors. The use of multiple bone anchors increases the footprint over which the suture material presses the soft tissue against bone. One non-limiting example, depicted in FIG. **2**, includes two bone anchors. One anchor **20** is positioned in a medial location underneath the soft tissue **12** and a second anchor **22** is positioned lateral to the soft tissue **12**. The suture **10** is attached to both anchors.

In one embodiment, the suture **10** is attached to the lateral bone anchor **22** only after the medial bone anchor **20** is inserted and the suture **10** is passed over the soft tissue **12**. In one embodiment, the suture **10** is attached to the medial bone anchor **20** prior to insertion of the medial bone anchor **20**. Thus, in this embodiment, the surgeon does not need to pass the suture through the soft tissue **12** from beneath the soft tissue **12**. In one embodiment, the procedure involves inserting the medial bone anchor **20** with suture **10** pre-attached through the soft tissue **12**. The medial bone anchor **20** may then be moved laterally relative to the bone **16** in order to pull the soft tissue **12** laterally relative to the bone **16**. After appropriate positioning of the soft tissue **12**, the medial bone anchor **20** may then be inserted into the bone **16**. The lateral bone anchor **22** may then be inserted into the bone **16**. The suture **12** may then be passed over the soft tissue **12** and attached to the lateral bone anchor **22**. In some embodiments, a lateral bone anchor **22** is provided to which suture **12** can be attached without tying any knots or without passing the suture **12** through any aperture in the lateral bone anchor **22**.

In some embodiments, multiple anchors and multiple suture lengths may used to provide a wider area of pressure of the soft tissue against bone. For example, as depicted in FIG. **3**A, three anchors are used with two lengths of suture **26** and **28**. Alternatively, a mesh structure **29** may be stretched between the three anchors. In another example, as depicted in FIG. **3**B, four anchors are used with two lengths of suture. In still another example, as depicted in FIG. **3**C, four anchors are used with four lengths of suture. In some embodiments, the individual suture lengths may be part of a larger continuous suture. For example, in FIG. **3**A, the suture lengths **26** and **28** may be part of a larger length of suture such that the lengths **26** and **28** are joined at medial bone anchor **20**. Those of skill in the art will appreciate that there are any number of anchor and suture geometries that can be used.

In some embodiments, the medial bone anchors **20** are designed so that they can be easily pierced through the soft tissue **12** and bone **16**. In some embodiments, the lateral bone anchors **22** are designed so that they can easily capture suture material after insertion of the bone anchors **22**. Together, these design features provide a suturing system and method that provides an increased footprint of suture pressure against the soft tissue **12** and ease of implementation for a surgeon. For example, in some embodiments, the entire procedure may be done arthroscopically, with the surgeon needing only to insert the medial bone anchor **20** with suture optionally pre-attached through a first port, insert the lateral anchor **22** through a second port, pass the suture over the soft tissue **12** by capturing it from within the second port, and securing the suture to the lateral anchor **22**. Accordingly, described below are certain embodiments of anchors adapted to capture suture material and anchors adapted to easily pierce through soft tissue and bone.

Suture Capturing Anchor

One embodiment is a bone anchor that allows easy capturing and securing of a suture after the bone anchor is inserted into the bone. In one embodiment, the bone anchor includes a suture securing mechanism positioned on the proximal end of the bone anchor (i.e., the end nearest the surface of the bone and the surgeon). In one embodiment, the suture securing mechanism allows a suture to be moved laterally into the

mechanism. By "laterally," it is meant that the suture can be moved into the mechanism by moving the suture in a direction that is generally perpendicular to the axis of the suture. In other words, the suture can be moved into the mechanism without threading an end of the suture into the mechanism. In one embodiment, the suture can be fixedly secured within the mechanism without tying any knots. By "fixedly secured," it is meant that the suture within the securing mechanism cannot be easily moved relative to the bone anchor.

One embodiment is a bone anchor that allows easy attachment of suture material by clamping the suture material between two surfaces on the bone anchor. The bone anchor may be configured such that the bone anchor is inserted into the bone without the suture material attached. The two surfaces of the suture securing mechanism may be spaced apart so as to form a gap between the surfaces. The suture material may be passed between the two surfaces and tensioned as desired followed by clamping of the two surfaces together, thereby clamping the suture material there between.

In one embodiment, the bone anchor consists of two parts: an anchor base and an anchor top. The anchor base may be designed to be inserted into a hole in the bone with a proximal surface facing up. The anchor top may be coupled to the anchor base via a distal member. A proximal member on the anchor top may have a distal surface facing down toward the proximal surface on the anchor base. The coupling of the anchor top to the anchor base may be such that the anchor top can move relative to the anchor base such that it can be positioned in one configuration where there is space between the proximal surface on the anchor base and the distal surface on the proximal member of the anchor top. In another configuration, the proximal member of the anchor top may be position such that there is very little space, if any, between the proximal surface on the anchor base and the distal surface on the proximal member of the anchor top. Thus, in the first configuration, suture material may be easily passed between the two surfaces and tensioned as desired. In the second configuration, the suture material may be clamped between the two surfaces such that the suture is secured to the bone anchor.

One embodiment of an anchor base **100** is depicted in FIGS. **4**A through **4**D. FIG. **4**A is a perspective view showing the side **101** and bottom **102** of the anchor base **100**. The bottom **102** of the anchor base **100** may advantageously be tapered to facilitate insertion of the anchor base **100** into bone. In some embodiments, a hole is predrilled into the bone to facilitate insertion of the anchor base **100**. In other embodiments, the anchor base **100** is forced directly into the bone, thereby creating the hole. The sides **101** of the anchor base **100** comprise threads **104** so that the anchor base **100** may be inserted into bone using a screwing action. In some embodiments, the anchor base **100** may be tapped to start the threads **104** into the bone followed by screwing the anchor base **100** into the bone. When the hole in the bone is pre-drilled, the hole is advantageously drilled with a diameter smaller than the diameter of threads **104** so that the threads engage the bone through the sides of the hole. It will be appreciated that means other than threads may be used to secure the anchor base **100** to bone. For example, angled protrusions may be used that provide greater resistance to removal of the anchor base **100** than to insertion. The protrusions may be static or deployable once the anchor is inserted.

The top of anchor base **100** preferably includes a structure **106** for facilitating the driving or screwing of the base **100** into the bone. In the illustrated embodiment, this comprises a hex nut structure **106** that facilitates engagement with a hex nut driver for screwing the anchor base **100** into the bone. It will be appreciated that other structures known in the art for engaging tools used for screwing action may be used instead of hex nut structure **106**, and that this structure can be indented into or extending out from the top of the anchor base **100**, or can alternatively be formed on the sides of the anchor base **100**.

With reference to FIG. **4**B, which is a perspective view of the top and side of anchor base **100**, the top (proximal end) comprises a hole **108** in the center for receiving the anchor top, which is described below. The top of anchor base **100** also contains a suture gripping structure such as a circular groove **110** that may be concentric with hole **108**. Because of groove **110**, the proximal surface of anchor base **100** is not flat and comprises top surfaces **112** and **114**, bottom surface **116**, and side surfaces **118** and **120**. In some embodiments, some or all of these surfaces may be textured such as with a scallop shape or grooves so as to inhibit movement of suture material pressed against the surfaces. Although a grooved surface is illustrated, it will be appreciated that other shapes for the proximal surface of anchor base **100** are also contemplated, including multiple concentric grooves, a series of protruding ridges, a "vee" shaped channel, or any other suitable structure that permits a suture to be securely locked against the top or proximal end of the anchor base **100**.

Hole **108** in anchor base **100** is an opening into a central ("axial") bore into the anchor base **100**. The sides of the central bore preferably include structures for gripping something inserted into the central bore, such as ratchet structures **122**. FIG. **4**C show a central ratchet bushing **126** that fits within the central bore and contains the ratchet structures **122**. In the embodiment of FIG. **4**C, the ratchet structures **122** are constructed by cutting U shaped cuts into bushing **126**. The U shaped cuts then define tabs that make up the ratchet structures **122**. It will be appreciated that other shapes and methods for making ratchet structures may be used. The purpose of ratchet bushing **126** is to receive the anchor top and secure it to the anchor base **100**. It will be appreciated that other methods of securing the anchor top to the anchor base **100** may be used, such as a frictional fit or threading. Furthermore, the anchor top may be coupled to the anchor base **100** using means other than hole **108** and bushing **126**. For example, the anchor top may be coupled via structures at the perimeter rather than the center or by a hinge.

FIG. **4**D depicts a cross section through the center of anchor base **100**. This view illustrates central bore **130** and groove **110**. The proximal surfaces **112**, **114**, **116**, **118**, and **120** are also apparent. Central bore **130** preferably does not extend all the way through the anchor base **100**. Instead, a smaller bore **132** is present at the distal end **102** of the anchor base **100**. Smaller bore **132** is used to receive a wire connected to an anchor inserter. It will be appreciated that other structures than bore **132** may be used for attaching the wire and that other means than a wire may be used to secure the anchor to the anchor inserter.

FIGS. **5**A through **5**C illustrate one embodiment of an anchor top **200**. FIG. **5**A provides a perspective view of the side and top of the anchor top **200** and FIG. **5**B provides a perspective view of the side and bottom of the anchor top **200**. Anchor top **200** has two members, a distal member **202** and a proximal member **204**. The distal member **202** comprises an elongated shaft, the longitudinal direction of which shall be considered to run along the axis of the distal member **202**. A series of grooves or other mating or locking surfaces or structures **206** exist along a portion of the outside surface of the shaft. The distal member **202** is designed to be inserted into the central bore **130** of the anchor base **100**. The ratchet structures **122** in the anchor base **100** engage grooves **206** to

couple the anchor top **200** to the anchor base **100**. The ratchet structures **122** are oriented such that the distal member **202** can be easily moved in the distal direction in central bore **130** with the ratchet structures **122** snapping into the grooves **206** as the distal member **202** is moved downward. However, when the ratchet structures **122** are snapped into grooves **206**, proximal movement of distal member **202** is inhibited. Thus, the anchor top **200** may be ratcheted down into anchor base **100**. Because the ratchet structures **122** exist along substantially the entire surface of the central bore **130** (see FIG. **4**C), the anchor top **200** may be coupled to the anchor base **100** in several positions. In other words, in one embodiment the anchor top **200** need not be ratcheted into the anchor base **100** as far as it will go for it to be secured to the anchor base **100**.

The proximal member **204** of anchor top **200** is generally cylindrical in shape with a diameter larger than distal member **202**. A hole **208** may advantageously be provided in the center of proximal member **204**. With reference to FIG. **5**B, the bottom of distal member **202** also contains a hole **210**. Holes **208** and **210** open into a central bore through the anchor top **200**. This central bore allows the wire referred to above to extend through the anchor top **200** to be secured to bore **132** in the anchor bottom **100**, thus allowing the anchor bottom **100** to be attached to an anchor inserter while still allowing anchor top **200** to be ratchet into anchor bottom **100**. FIG. **5**B also illustrates that proximal member **204** contains a groove **212** in its distal surface. Thus, the distal surface of proximal member **204** is not flat and comprises distally facing surfaces **214** and **216** and side facing surfaces **218** and **220**. In some embodiments, some or all of these surfaces may be textured such as with a scallop shape or grooves so as to inhibit movement of suture material pressed against the surfaces. In some embodiments, texturing in the distal surfaces of proximal member **204** match texturing in the proximal surfaces of anchor base **100**. It will be appreciated that the illustrated embodiments represent only one possibility; thus, other shapes for the distal surface of proximal member **204** may also be used. FIG. **5**C depicts a cross section through the center of anchor top **200**. In this figure, the central bore **226** is depicted as are surfaces **214**, **216**, **218**, and **220** and grooves **206**.

FIGS. **6**A and **6**B depict cross sections showing how the anchor top **200** may be coupled to anchor base **100** to form the complete anchor **300**. In FIG. **6**A, the anchor top **200** is coupled to anchor base **100** with the proximal member **204** separated from the anchor base **100**. The anchor top **200** is secured to anchor base **100** by distal member **202** extending into central bore **130** of the anchor base **100**. The distal member **202** is secured by ratchet structures (not shown) engaging grooves **206** in distal member **202**. Central bore **226** in anchor top **200** and central bore **130** in anchor base **100** allow a wire to extend into the top of the anchor **300** and be secured to bore **132**. Alternatively, the wire may be secured at other locations within central bore **130**. Thus the wire, which can be coupled to an anchor inserter, can hold the entire anchor assembly **300** and still allow anchor top **200** to move relative to anchor base **100** and the wire.

FIG. **6**B depicts the anchor assembly **300** with the distal member **202** of anchor top **200** ratcheted all the way into central bore **130** in anchor base **100**. In this configuration, it can be seen that proximal surfaces **112**, **114**, **116**, **118**, and **120** of the anchor base **100** and distal surfaces **214**, **216**, **218**, and **220** of the proximal member **204** of anchor top **200** form passageways **302** and **304**. The size of passageways **302** and **304** are advantageously such that when a suture passes through them, it will be compressed so that it is securely attached to the anchor **300**.

Another embodiment of the present invention is an inserter designed to insert and manipulate an anchor such as described in FIGS. **1**-**3**. One such inserter **400** is depicted in FIGS. **7**A and **7**B. Inserter **400** comprises a handle **402** and an outer tube **404**. As depicted in FIG. **7**A, the handle **402** comprises a cover **403**. FIG. **7**B depicts the inserter **400** with cover **403** removed. Not depicted in FIGS. **7**A and **7**B are an inner tube disposed inside outer tube **404** and a wire disposed within the inner tube. As will be described in more detail below, the inner and outer tubes may be used to manipulate an anchor **300** such as that described in FIGS. **4**-**6**. The wire may be used to couple the inserter **400** to the anchor **300** as described above. Inserter **400** also comprises an outer tube manipulator **406** and a wire manipulator **408**. Outer tube manipulator **406** comprises release button **410**. Outer tube manipulator **406** is securely attached to outer tube **404**. Outer tube manipulator **406** may move longitudinally relative to handle **402** and the inner tube when release button **410** is pressed. Thus, when outer tube manipulator **406** is moved, outer tube **404** also moves.

Wire manipulator **408** comprises wire grabber **410** to which the wire is attached. The wire extends from wire grabber **410**, through handle **402**, and then through the inner tube. In one embodiment, wire manipulator **408** also comprises a release button **412**. When release button **412** is pressed, the wire manipulator **408** may be pressed into the handle **402** to contact and thus provide additional tension on the wire. When in use, the additional tension causes the anchor base **100** to mover relative to inserter **400**. When enough tension is provided to the wire by wire manipulator **408**, the wire may break free from the anchor **300** at its attachment point in bore **132** or at some other predetermined location along the wire. It will be appreciated that any suitable breakable attachment means may be used for securing the wire to the anchor **300**. For example, the wire may be frictionally secured into bore **132** or it may welded to the anchor base **100** using a weld that is weaker than the wire itself or a portion of the wire where breaking is desired may be weakened. In one embodiment, the wire is notched so as to create a weaker region in the wire that will break upon application of suitable force.

The tip **414** of outer tube **404** is depicted in more detail along with inner tube **420**, wire **422**, and anchor **300** in FIG. **8**. The end of outer tube **404** may comprise a hex nut driver structure **424** for receiving the hex nut structure **106** of anchor base **100**. Of course, any other suitable engagement structure can be provided on the inserter **400** and the anchor base **100** in order to facilitate placement of the anchor base **100**. Wire **422** extends out of inner tube **420** and into the central bore in the anchor top **200** to attach to anchor base **100** as described above. In some advantageous embodiments, the wire length and tension is adjusted such that the proximal member **204** of anchor top **200** buts against the end **426** of inner tube **420**.

FIGS. **9**A through **9**E depict how inserter **400** and anchor **300** may be used to insert the anchor **300** into bone and attach a suture to it. FIG. **9**A depicts the configuration for inserting the anchor **300** into bone. Outer tube **404** and outer tube manipulator **406** (see FIGS. **7**A and **7**B) are positioned relative to inner tube **420** and handle **402** (see FIGS. **7** and **8**) so that the outer tube **404** engages hex nut structure **106** in the anchor base **100**. It is advantageous in this configuration for the anchor top **200** to be in a position relative to the anchor base **100** such as depicted in FIG. **6**A. In the configuration of FIG. **9**A, a surgeon may then screw the anchor base **100** into bone by twisting handle **402** of inserter **400** (see FIGS. **7**A and **7**B).

After the anchor base **100** is inserted into the bone, the outer tube **404** may be slid backward relative to the inner tube **420** and handle **402** to expose the anchor top **200** such as in

FIG. **9**B. One or more lengths of suture **600** may then be placed in the space between the distal surface **602** of the proximal member **204** of anchor top **200** and the proximal surface **604** of the anchor base **100** by moving the suture laterally into the space as depicted in FIG. **9**C. The suture **600** may be manually tensioned as desired. In some embodiments, tensioning of the suture **600** is aided by pulling the suture **600** against the distal member **202** of the anchor top **200**.

After appropriate tensioning of suture **600**, wire manipulator **408** may be pressed to tension the wire, causing the handle **402** of the inserter **400** and the inner tube **420** to be pulled down towards the anchor base **100** so that inner tube **420** ratchets the anchor top **200** down into the anchor bottom **100** as depicted in FIG. **9**D. As the anchor top **200** is pushed axially down, suture **600** will be clamped between the distal surface **602** of the proximal member **204** of anchor top **200** and the proximal surface **604** of the anchor base **100** (see also FIG. **9**C). The clamping will force the suture to be compressed within the passageways **302** and **304** depicted in FIG. **6**B and thus be secured to anchor **300**. The fit between the anchor top **200** and the anchor base **100** in the clamping region is such that the suture **600** is firmly gripped, but is not cut, when it is clamped in place. Appropriate edges that may contact the suture are preferably beveled or rounded to avoid damage to the suture. After anchor top **200** is ratcheted sufficiently into anchor base **100**, wire manipulator **408** (see FIGS. **7**A and **7**B) in inserter **400** may be compressed further to further tension wire **422** (see FIG. **8**) such that wire **422** breaks free from its attachment to anchor base **100**, thus leaving the anchor **300** free from inserter **400** with suture **600** securely attached as depicted in FIG. **9**E.

Although a particular inserter device for inserting and manipulating anchor **300** has been described, it should be understood that other inserter designs may be used for manipulating the parts of anchor **300** described above to insert the anchor into bone and secure suture material to the anchor. For example, it may be possible to use separate tools for inserting the anchor and securing the suture material. In addition, in alternative embodiments, the anchor base **100** may be connected to the anchor top **200** throughout the procedure, or the anchor base may be separately inserted into the bone, and the anchor top can be attached thereafter by axially sliding the distal end of the anchor top **200** into the hole **108** in the anchor base **100**.

It will be appreciated by those of skill in the art that the anchor **300** and inserter **400** provide a system for easy attachment of a suture to bone. The anchor **300** may be inserted into bone with minimal disruption of surrounding tissue. Only an access route having the diameter of the outer tube **404** and the anchor base **100** is required. Furthermore, the suture can be securely attached to the anchor **300** and tensioned as desired without having to insert additional instrumentation into the site or without performing any cumbersome attachment maneuvers such as knot tying. It should also be appreciated that the general principle illustrated by this system of inserting an anchor into bone without having suture material pre-attached and then attaching suture to the anchor without tying any knots may be implemented using any appropriate system other than the specific embodiments depicted in FIGS. **4**-**9**.

Tissue and Bone Piercing Anchor

One embodiment is a bone anchor adapted for piercing through the soft tissue and into underlying bone. In one embodiment, the suture material may be pre-attached to the piercing bone anchor so that after implantation, a suture passes from the bone anchor through to the top of the soft tissue for easy passing over the soft tissue. In one embodiment, the piercing bone anchor has two configurations, a first configuration having a small diameter for easy piercing through soft tissue and bone and a second deployed configuration where structures such as protrusions are deployed to prevent the bone anchor from being easily removed from the bone.

In one embodiment, the anchor includes a substantially hollow cylinder having a portion of its walls cut in such a manner so as to allow the cylinder to deform under axial stress and form lateral protrusions. The lateral protrusions may thus prevent the anchor from being easily removed from the bone after deployment. In one embodiment, the anchor comprises a pointed tip coupled to the hollow cylinder for piercing the soft tissue and bone. In one embodiment, suture is pre-attached to the pointed tip inside of the hollow cylinder. In other embodiments, suture is pre-attached at other locations on the piercing anchor, such as at the proximal end of the hollow cylinder.

One embodiment of a deployable piercing anchor is depicted in FIGS. **10**A and **10**B. In FIG. **10**A, the anchor is depicted in a pre-deployed state. The anchor includes a substantially hollow cylinder **650** with a plurality of cuts **652** in the side of the cylinder **650**. The cylinder **650** is open on one end **654**. On the other end, a pointed tip **656** is disposed, allowing the anchor to pierce through soft tissue and bone. In FIG. **10**B, the anchor is depicted in a deployed state. Stress is applied in an axial direction such that the cylinder **650** collapses along cuts **652** so as to form two lateral wings **660**. The lateral wings **660** prevent the anchor from being removed from the bone. Hinges **662** connect one end of each wing to either the top or the bottom parts of anchor body. These hinges deform and fold, in the plane tangent to the anchor body at that point when the anchor is deployed. A strip of material **664** connects the top and bottom wing on each side of the anchor body, and serves as a hinge between the two as well as aiding in alignment of the wings during deformation. The tips of the wings adjacent to the connecting strip **664** utilize rolling edges **666**, which ensure uniform alignment and smooth transition during deformation. Those of skill in the art will appreciate that any number of geometries of cuts in the cylinder **650** may be utilized to create a deformable structure that will produce lateral protrusions upon exposure to stress.

In some embodiments, structures may be positioned within the cylinder **650** for attaching sutures and engaging with an anchor inserter. In one embodiment, such structures are coupled to the anchor tip **656** within the cylinder **650**. FIG. **11** depicts one such embodiment. Attached to the tip **656** is a structure **670** through which there is an aperture **672**. The structure **670** may be adapted to engage the inner surface of cylinder **650** for attaching the tip **656** to the cylinder **650**. The attachment mechanism may be by forced fit, frictional fit, threads, welding, adhesive, or any other suitable means. Suture material may be threaded through the aperture **672** in order to attach the suture to the anchor. The suture material may be secured to the tip **656** by tying the suture around structure **670**, tying a knot in the end of the suture that prevents it from being pulled through the aperture **672**, clamping the suture between the structure **670** and the inside of the cylinder **650**, adhering the suture to structure **670** by welding or adhesive, or any other suitable means. In one embodiment, the suture material is attached to the anchor at tip **656** prior to use of the anchor.

An anchor inserter attachment structure **674** may also be coupled to the tip **656**. This structure **674** may couple to an anchor inserter through a wire or any other suitable means. The attachment between the anchor inserter and the anchor at this point may be used to apply axial stress to the anchor for

deploying the anchor as described above. The attachment at this point may also serve to keep the anchor attached to the inserter prior to deployment.

One embodiment of an anchor inserter suitable for use with the above-described anchor is depicted in FIG. **12**. The anchor inserter comprises a grasping handle **700** to which is attached an outer sleeve **702** which is fixed relative to the handle **700**. The piercing anchor **704** is disposed at the end of the sleeve **702**. A deployment lever **706** may be pressed by a user to deploy and detach the anchor **704** as described below. A safety switch **708** may be provided to prevent the anchor **704** from being deployed prematurely. A spool **710** may be provided at the proximal end of the handle **700** for holding excess suture. A lid **712** may be provided for gaining access to the inner components of the inserter.

FIG. **13** depicts the anchor **704** coupled to the inserter. As described above, the anchor **704** comprises a hollow cylinder **650** with cuts in the sides and a pointed tip **656**. Furthermore, as depicted in FIG. **11**, a suture receiving aperture **672** and an inserter attachment structure **674** are attached to the pointed tip **656** within the cylinder **650**. The outer sleeve **702** of the inserter may fit over the open end **654** of the cylinder **650** or be flush with the open end **654**. The outer sleeve **702** may thus hold the top part of the anchor **704** steady during insertion. In an alternative embodiment, the outer sleeve **702** may fit over the length of the cylinder **650** to prevent the cylinder **650** from deforming while it is being inserted into bone. In this alternative embodiment, the outer sleeve **702** may be retracted prior to deployment of the anchor. An inner tube **720** may be positioned within the outer sleeve **702** and the hollow cylinder **650** and contact the top surface of the anchor tip **656** (see FIG. **11**). The inner tube **720** provides structural reinforcement of the anchor **704** and pushes against the tip of the anchor **704** while it is being driven into bone or tissue. The inner tube **720** may be fixed relative to the handle **712** and outer sleeve **702** during insertion, however, during deployment of the anchor **704**, the inner tube **720** may be released by switching safety switch **708** so that the inner tube **720** can move axially relative to the outer sleeve **702** while the anchor cylinder **650** collapses. A wire may be positioned inside of the inner tube **720** running from within the handle **712** through the inner tube **720** to the anchor **704** and attached to the anchor inserter attachment structure **674**. During deployment, the lever **704** may be pressed to pull the wire axially towards the handle **700**. The axially movement of the wire forces the anchor **704** to press against outer sleeve **702** and stresses the cylinder **650**, causing it to deform and deploy. During collapse of the cylinder **650**, the inner tube **720** will also move in an axial direction toward the handle **700**. Upon further stress on the wire, the wire may break free from the anchor inserter attachment structure **674**, releasing the inserter from the anchor **704**. Suture material may run from the inside of handle **700** through the inner tube **720** to attach to the anchor **704** through aperture **672** (see FIG. **11**). Upon detachment of the anchor inserter from the anchor **704**, the inserter may be withdrawn, leaving the inserted and deployed anchor with suture coming out of the open end **654** of the cylinder **650**. The suture will still be coupled to the inserter through the inner tube **720**, handle **700**, and around spool **710**. Those of skill in the art will appreciate other inserters and mechanisms that may be used to insert and deploy the piercing anchors described herein. For example, rather then axially stressing the anchor **704** by pulling the tip **656** in an proximal direction, the cylinder **650** may be pushed in a distal direction to deform the cylinder **650**.

FIG. **14** is a cut-away view of the handle **700**, showing the inner workings of the anchor inserter. The suture material attached to a piercing anchor at the tip of the inserter may pass through the central bore of the inner tube **720** and through a bore **750** in the handle **700**. The suture material may then pass through a hole **752** in the end of the handle **700** and be wrapped around the spool **710**, which may be integral with the handle **700**. The wire attached to the anchor inserter attachment structure **674** in the anchor may also pass through the central bore of the inner tube **720** and may then proceed around a pulley **754** and attach securely to the handle **700** at point **756**. The pulley **754** may be attached to the lever **706**. When the lever **706** is pressed down, the pulley **754** will move toward the back end of the handle **700**, causing the wire attached to the anchor to retract. Because of the use of pulley **754**, the wire will retract twice the distance as the pulley **754** moves.

The safety switch **708** may be used to prevent the lever **706** from being pressed and prevent the inner tube **720** from moving unless the safety switch **708** is in the correct position. The safety mechanism operates via a drum **760** disposed within the handle **700** to which the safety switch **708** is attached. Moving the safety switch **708** rotates the drum **760** within the handle **700**. FIG. **15** shows the drum **760** and safety switch **708** mechanism in more detail. The inner tube **720** passes through a central bore in the drum **760**. On the other side of the drum **760**, the inner tube **720** is attached to a stopper **762**. The stopper **762** has a through-hole **764** to permit passage of the deployment wire and suture. The stopper **762** may be positioned within a cavity **766** in the end of the drum **760**. A second similarly shaped cavity may be disposed within the handle **700**. The stopper **762** and attached inner tube **720** may only be allowed to move axially relative to the handle **700** when the safety switch **708** and drum **760** is rotated so that the cavity **766** in the drum **760** is aligned with the matching cavity in the handle **700**. When the cavities are aligned, the stopper **762** is allowed to move from the cavity **766** to the cavity in the handle **700**, thus allowing the inner tube **720** to move axially and the anchor to be deployed.

Additionally, the drum **760** comprises a groove **768**. A spring-loaded sliding pin **770** (see FIG. **14**) may be coupled to the lever **706**. The lever **706** can only be moved when the drum **760** and switch **708** are rotated so that groove **768** is aligned with the pin **770**. Thus, both the stopper **764** and the pin **770** prevent the anchor from being deployed unless the switch **708** is in the correct position.

Those of skill in the art will appreciate other mechanisms that could be used for deploying a deployable anchor and providing safety mechanisms to prevent premature deployment.

Example Using a Piercing Anchor and a Suture Capturing Anchor

The above-described anchors may be used in a surgical procedure for attaching soft tissue to bone. One example of such a procedure is depicted in FIGS. **16**A through **16**F. In FIG. **16**A, the piercing anchor **800** attached to an anchor inserter **802** as described above is pierced through soft tissue **804** that has become detached from underlying bone **806**. In FIG. **16**B, the anchor inserter **802** is moved laterally relative to the bone **806** so as to stretch the soft tissue **804** laterally relative to the bone **806**. Once the soft tissue **804** has been stretched to the desired position, the anchor **800** is inserted into the bone **806** and the anchor **800** is deployed as described above and the inserter **802** is detached from the anchor **800**, leaving a suture **808** attached to the anchor **800** and extending through the soft tissue **804**. The anchor **800** may be inserted into bone **806** by tapping on the inserter **802** with a hammer or by any other suitable means of applying axial force. FIG. **16**C depicts the deployed anchor **800** with attached suture **808**. The suture **808** will extend into the inserter **802**.

Next, as depicted in FIG. **16**D, a suture capturing anchor **810** is inserted into the bone **806** using the inserter **812** as described above. In FIG. **16**E, the inserter **812** is then retracted to expose the suture capturing mechanism. The suture **808** is then passed over the soft tissue **804** and laterally moved into the suture capturing mechanism and tensioned. Finally, as depicted in FIG. **16**F, the suture capturing mechanism is deployed to capture the suture **808**, the anchor inserter **812** is detached from the anchor **810**, and the suture **808** is cut to detach it from the suture inserter **802**. The result is a length of suture **808** between the bone anchors **808** and **810** that presses the soft tissue **804** against the bone **806**. Multiple anchors and sutures may be used to produce geometries such as depicted in FIGS. **2** and **3** and variations thereof.

It will be appreciated that there are numerous stitches, suture threading patterns, and anchor patterns that may be used to secure soft tissue to bone by the methods and devices described herein. These variations as well as variations in the design of the above described anchor devices and inserter devices are within the scope of the present disclosure.

Methods of Attaching Soft Tissue to Bone

Various embodiments include methods for attaching soft tissue to bone. In some embodiments, the methods include using the bone anchors described above. In one embodiment, a bone anchor is inserted into the bone and then a length of suture is passed over the soft tissue and secured to the anchor after inserting the anchor without tying any knots or without passing the suture through an aperture in the anchor. In some embodiments, the suture is secured to the anchor by laterally moving it into a securing mechanism. In one embodiment, securing the suture to the anchor includes clamping the suture between at least two surfaces on the anchor. In one embodiment, the anchor is not inserted further into the bone after securing the suture to it.

In another embodiment, a first anchor with a suture pre-attached is inserted through the soft tissue and into the bone. The suture may then be passed over the soft tissue and fixedly secured to a second bone anchor. In one embodiment, the first anchor is inserted by directly piercing the soft tissue and the bone. In one embodiment, lateral protrusion may be deployed on the first anchor to prevent the first anchor from being removed. In one embodiment, the suture may be coupled to the second bone anchor prior to insertion and then fixedly secured after insertion. In this context, "coupled" means that the suture is attached to the bone anchor but not fixedly secured, such that the suture can move to some extent relative to the bone anchor. In an alternative embodiment, the suture is not coupled to the second bone anchor during its insertion.

In another embodiment, a first portion of suture is inserted into the proximal surface of the soft tissue. A second portion of the suture (e.g., the portion proximal to the inserted portion) is then passed over the proximal surface of the soft tissue and fixedly secured to a bone anchor. In one embodiment, the procedure may be performed without passing the first portion of the suture back out of the proximal surface of the soft tissue. In one embodiment, this result is accomplished by the first portion of the suture being attached to an anchor that is inserted through the soft tissue and into bone.

One embodiment includes inserting a first anchor with a pre-coupled suture through soft tissue and into bone. The suture may then be passed over the soft tissue and fixedly secured to a second anchor. In one embodiment, the pre-coupled suture is fixedly secured to the first anchor prior to insertion. In an alternative embodiment, the pre-coupled suture can move relative to the first anchor prior to insertion and is fixedly secured after insertion.

In another embodiment, multiple lengths of suture are attached to multiple anchors. In one embodiment at least three anchors are inserted into bone. A first length of suture may be secured between a first and second anchor and a second length of suture may be secured between the first and a third anchor. In one embodiment, the first anchor is positioned beneath the soft tissue and the second and third anchors are positioned laterally to the soft tissue. In an alternative embodiment, the first anchor is positioned laterally to the soft tissue and the second and third anchors are positioned beneath the soft tissue. In some embodiments, the lengths of suture are fixedly secured to the anchor(s) positioned beneath the soft tissue prior to insertion of those anchor(s). In one embodiment, the different lengths of suture may be tensioned separately.

In various embodiments, prior to fixedly securing suture to a bone anchor, it can be tensioned. In one embodiment, tensioning is accomplished by manually pulling on the suture such as by a surgeon grasping the suture using an appropriate instrument and then pulling. In one embodiment, the suture may be pressed against the bone anchor to provide leverage for pulling. For example, the suture may be wrapped partly around a proximal portion of the anchor prior to pulling.

Although the invention has been described with reference to embodiments and examples, it should be understood that numerous and various modifications can be made without departing from the spirit of the invention. Accordingly, the invention is limited only by the following claims.

What is claimed is:

1. A method of attaching soft tissue to bone, comprising:
- inserting a first anchor into bone, wherein after insertion, the first anchor is positioned underneath the soft tissue;
- passing a first length of suture from said first anchor over the soft tissue;
- inserting at least a portion of a second anchor into bone at a position beyond an edge of the soft tissue;
- after inserting said at least a portion of the second anchor, tensioning the first length of suture to compress an area of tissue to bone between the edge of the soft tissue and the first anchor; and
- after tensioning the first length of suture, fixedly securing the first length of suture at the second anchor position without tying any knots;
- wherein at least one of said anchors comprises an anchor tip and a hollow cylinder, wherein the anchor tip comprises an aperture through which suture material is threaded prior to insertion of the at least one anchor.

2. The method of claim **1**, wherein said anchor tip comprises an engaging member adapted to engage an inner surface of said cylinder.

3. The method of claim **1**, wherein said anchor tip comprises an anchor inserter attachment member.

4. The method of claim **3**, wherein insertion of the at least one anchor comprising an anchor tip and a hollow cylinder comprises using an inserter that comprises a handle, an outer sleeve, and an inner member, wherein the inner member extends through the outer sleeve and the hollow cylinder and is attached to the anchor inserter attachment member.

5. The method of claim **4**, wherein the inserter comprises an inner tube extending through the outer sleeve and through the hollow cylinder and contacts the anchor tip, wherein the inner member extends through the inner tube.

6. The method of claim **5**, wherein the inner tube is fixed relative to the handle.

7. The method of claim **5**, wherein the inner tube is movable axially relative to the outer sleeve.

8. The method of claim 5, wherein suture material runs from inside the handle of the inserter, through the inner tube, and through the aperture in the anchor tip.

9. The method of claim 8, wherein the suture material runs through a bore in the handle and passes through a hole in an end of the handle.

10. The method of claim 9, wherein the handle comprises a spool at a proximal end of the handle adapted to hold excess suture.

11. The method of claim 10, wherein the suture material is wrapped around the spool.

12. The method of claim 11, wherein the spool is integral with the handle.

13. The method of claim 4, wherein insertion of the at least one anchor comprising an anchor tip and a hollow cylinder comprises tapping on the inserter with a hammer.

14. The method of claim 1, comprising coupling the first length of suture to the at least one anchor comprising an anchor tip and a hollow cylinder prior to inserting the at least one anchor comprising an anchor tip and a hollow cylinder.

15. The method of claim 1, wherein the tensioning comprises manually pulling on the first length of suture.

16. The method of claim 1, comprising:

inserting a third anchor into bone, wherein after insertion, the third anchor is positioned underneath the soft tissue;

passing a second length of suture from said third anchor over the soft issue;

tensioning the second length of suture independently from the first length of suture; and

after tensioning the first and second lengths of suture, fixedly securing both the first and second lengths of suture at the second anchor position without tying any knots.

17. A method of attaching soft tissue to bone, comprising:

inserting a first anchor into bone, wherein after insertion, the first anchor is positioned underneath the soft tissue;

passing a first length of suture from said first anchor over the soft tissue;

inserting at least a portion of a second anchor into bone at a position beyond an edge of the soft tissue;

after inserting said at least a portion of the second anchor, tensioning the first length of suture to compress an area of tissue to bone between the edge of the soft tissue and the first anchor; and

after tensioning the first length of suture, fixedly securing the first length of suture at the second anchor position without tying any knots;

wherein at least one of said anchors comprises an anchor tip and a hollow cylinder, wherein the anchor tip comprises:

an aperture through which suture material is threaded prior to insertion of the at least one anchor,

an engaging member adapted to engage an inner surface of said cylinder, and

an anchor inserter attachment member, wherein insertion of the at least one anchor comprising an anchor tip and a hollow cylinder comprises using an inserter that comprises a handle, an outer sleeve, and an inner member, wherein the inner member extends through the outer sleeve and the hollow cylinder and is attached to the anchor inserter attachment member.

* * * * *

EXHIBIT 4

Technical Note

Mattress Double Anchor Footprint Repair: A Novel, Arthroscopic Rotator Cuff Repair Technique

Peter J. Millett, M.D., M.Sc., Augustus Mazzocca, M.D., and Carlos A. Guanche, M.D.

Abstract: In an effort to increase the immediate strength of a rotator cuff repair and to simulate the standard open reconstruction with its effective suture fixation, we have developed a novel technique for suture anchor reconstruction of the rotator cuff. The technique, termed mattress double anchor (MDA), is simple and adaptable. It makes use of 2 suture anchors that are placed independently and then connected by a suture loop. The technique produces a repair construct that distributes the stress across 2 anchors. The method also restores a large surface area for healing between the rotator cuff and the tuberosity. **Key Words:** Suture anchor—Rotator cuff repair—Rotator cuff footprint—Double row.

The surgical approach to the rotator cuff has evolved over the last several years and there is great interest in arthroscopic repair of rotator cuff tears. There are many techniques that have been developed to improve the initial strength of the repair. By increasing the initial repair strength, earlier and more aggressive rehabilitation can be allowed. Immobilization is decreased, which hastens recovery and return of function. Concerns about failure of fixation at the cuff-bone and the cuff-suture interface often lead surgeons to limit early motion.

The weak links in rotator cuff repair are at the cuff-suture interface and at the suture-bone interface. Several techniques have been developed to address these issues. Historically, the most notable are (1) the transosseous suture configuration, which compresses the cuff onto the tuberosity, and (2) the modified Mason-Allen suture grasping technique, which maximizes resistance to suture-tendon pullout.[1] In addition to strength, the technique of the repair has also been shown to affect the surface area of the repair, which undoubtedly affects the potential for healing between the cuff tendon and the underlying bone.[2] The footprint of the rotator cuff on the tuberosity is quite broad[3] at approximately 15 mm, and double row fixation has been advocated as a means to restore this surface area for healing.[4,5]

Most modern arthroscopic repair techniques have used suture anchors because of the technical difficulties with transosseous techniques.[6-8] Furthermore, most of the arthroscopic techniques rely on simple sutures through the rotator cuff tendon, which are undoubtedly a weak link.

In an effort to address many of these issues, we have developed a novel repair strategy that closely approximates both the transosseous suture configuration and the modified Mason-Allen tissue-grasping technique in an arthroscopic fashion. The technique simplifies suture management and eliminates the need to pass sutures multiple times. The purpose of this article is to describe the technique that we have termed the mattress double anchor technique (MDA).

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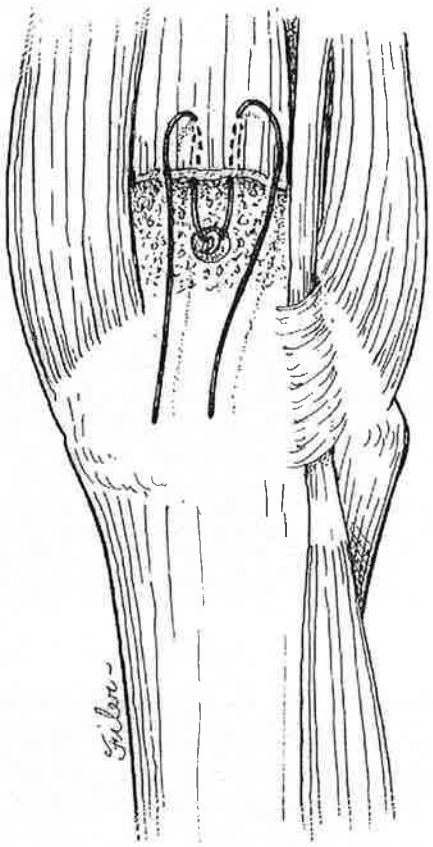

FIGURE 1. The medial anchor is placed in the medial border of the footprint at the articular margin and the sutures are passed in a mattress configuration so that there are anterior and posterior limbs. The sutures should be passed through the tendon 10 to 15 mm medial to the edge so that the desired amount of tendon will be repaired over the footprint.

TECHNIQUE

The standard approaches are used with respect to patient selection and decision-making regarding the possibility of an arthroscopic repair.[6-8] Once the decision is made to perform this type of repair, the surgeon should perform a thorough debridement of the rotator cuff, prepare the tuberosity by removing soft tissues, and plan the repair.

Following debridement of the edges of the cuff from an intra-articular and extra-articular position, a thorough bursectomy is performed. An acromioplasty is performed as needed. The rotator cuff footprint is re-established by debriding the greater tuberosity down to bleeding corticocancellous bone. No attempt is made to decorticate the area or to create a trough so as to avoid weakening the fixation points for the anchors.

The first anchor, termed the medial anchor, is placed at the articular margin. Tingart et al.[9] have recently shown

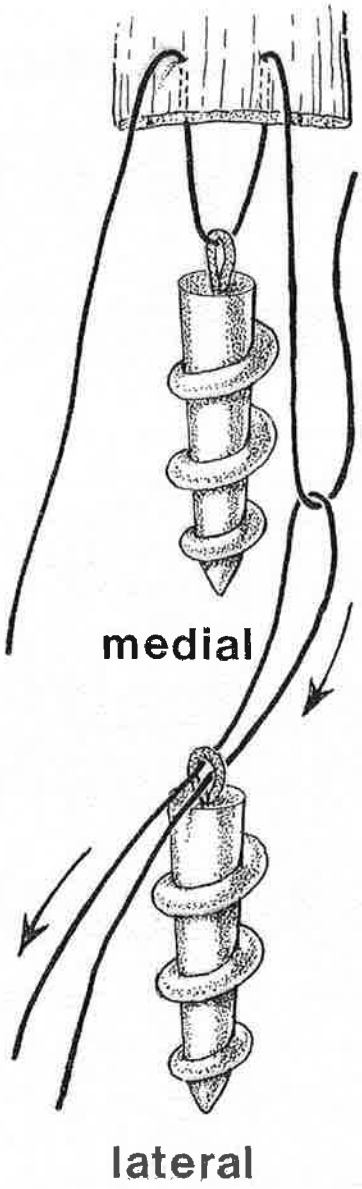

FIGURE 2. Illustration showing how the suture anchors are linked with a single suture. The lateral anchor must be preloaded with a loop of suture before insertion.

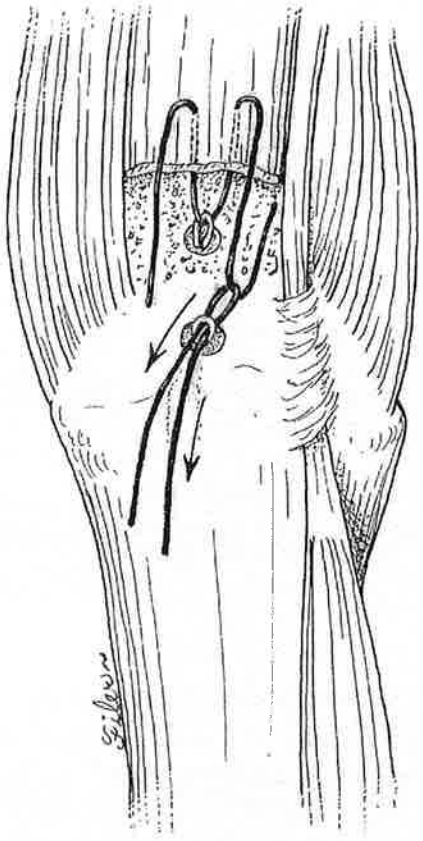

FIGURE 3. The lateral anchor is placed laterally on the tuberosity. One limb from the medial suture is pulled through the loop and then shuttled through the eyelet of the lateral anchor.

that this bone has the best quality with the highest bone mineral density.[9] The medial anchor is a 5.0-mm Biocorkscrew anchor (Arthrex, Naples, FL), although in cases where bone quality is an issue, a 6.5-mm Biocorkscrew anchor may be used. It is imperative to use an anchor with a suture eyelet because the technique requires that the sutures slide easily through the eyelets and requires the passage of a suture through the eyelet of the lateral anchor after the anchor has been inserted (in situ). An anchor with this type of eyelet design is essential. A metal eyelet will not permit passage of the sutures in situ and, furthermore, will not allow the sutures to slide easily, resulting in abrasion and possible breakage. The medial anchor should be loaded with 2 sutures (No. 2 Fiberwire, Arthrex) in order to repair the rotator cuff tendon with the use of a tissue-grasping technique.

As the medial anchor is placed, care is taken to align the eyelet of the anchor perpendicular to the articular margin. This area has the best bone quality of the tuberosity and ensures that the medial insertion of the rotator cuff will be re-established. This orientation of the anchor allows the sutures to be passed so that there will be anterior and posterior suture limbs that will slide easily (Fig 1). Suture passage through the rotator cuff is accomplished using any one of a variety of standard techniques.

The second anchor, termed the lateral anchor, is placed about 1 cm lateral to the first anchor. This anchor can be either a 5.0- or 6.5-mm Biocorkscrew, depending on the bone quality. This anchor should be inserted with a loop of suture across the eyelet, rather than 2 single limbs. The sutures should be preloaded in this configuration before insertion (Fig 2). One of the loops will be used to pass a suture from the medial anchor through the eyelet of the lateral in situ anchor (Fig 3). It is essential to assure that the suture is passed

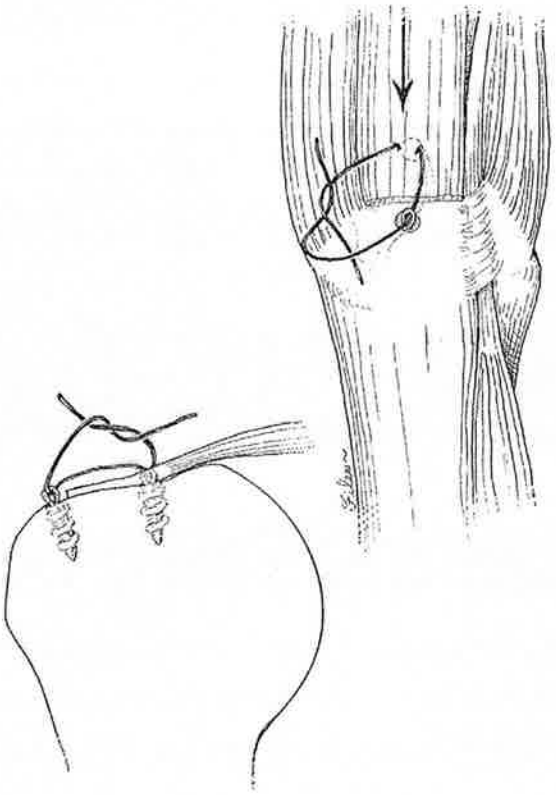

FIGURE 4. The suture linked between 2 anchors is then secured using standard arthroscopic knot tying techniques. The tendon is compressed onto the tuberosity and a broad footprint is recreated. In the coronal view, the configuration is similar to that achieved with transosseous techniques.

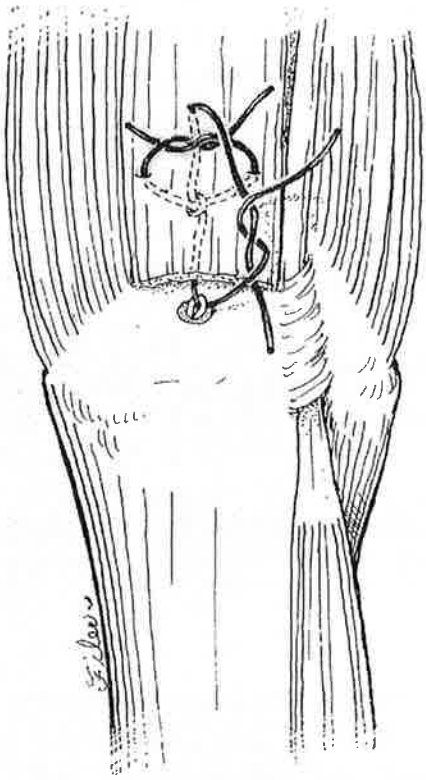

FIGURE 5. An alternative suture configuration with interlocking of the sutures to prevent cutout from the tendon.

in a medial-to-lateral direction through the lateral anchor, to avoid twisting the suture in the lateral anchor eyelet, because this would inhibit sliding and potentially compromise the repair. Knot tying is then accomplished with standard sliding locking knot techniques. This creates a mattress suture pattern between the 2 anchors that compresses the underlying rotator cuff, hence the term mattress double anchor (Fig 4).

One set of 2 anchors is used per centimeter.[7] The spacing of multiple anchors should be carefully planned to avoid overcrowding of the anchors in the tuberosity.

Alternative suture configurations can be used where a second suture is tied in a mattress configuration medially, where the sutures are oriented in a suture-grasping configuration similar to that described by P. St. Pierre (personal communication, October 2003) for a single-anchor technique (Fig 5), or where the sutures criss-cross between 2 sets of anchors creating maximum compression over a large surface area (Fig 6).

BIOMECHANICAL AND CLINICAL RESULTS

Biomechanical testing has been performed and shows this technique to be as strong as traditional single-row techniques with better restoration of surface area and less chance for bone failure.[10] It has strength similar to other double-row anchor patterns with fewer passes of suture through the rotator cuff. The authors have used the technique clinically in more than 50 cases without any adverse effects.

DISCUSSION

The MDA technique simulates a traditional transosseous repair with a tendon-grasping suture configura-

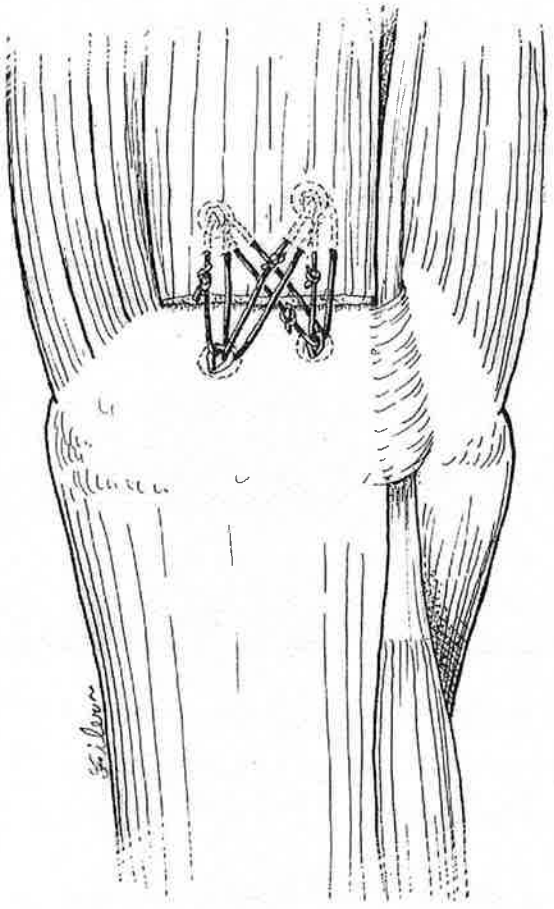

FIGURE 6. The complex criss-cross configuration where sutures from 4 separate anchors can be interlocked to maximize tendon compression and repair site surface area.

tion, yet it can be performed arthroscopically. The technique allows the reapproximation of the rotator cuff tendon solidly onto the greater tuberosity while increasing the area available for healing. Furthermore, the cross-linking of the anchors compresses the rotator cuff, decreases the risk of bone failure, minimizes the number of passes of sutures through the tendon, and eliminates prominent edges to the cuff. It seems likely that the construct decreases the chances of bone failure because of the increased number of fixation points.

The strength of the MDA and its restoration of the rotator cuff footprint are excellent. The MDA repair is as strong as traditional suture anchor techniques with better restoration of the footprint. The MDA technique is reproducible and easily performed by surgeons proficient in arthroscopic rotator cuff repairs. While the MDA technique is adaptable and can be carried out in different suture configurations and in open procedures, there are certain tears, such as chronic retracted tears, that may be better treated with single-row fixation or margin convergence to avoid excess tension on the repair.

In summary, the MDA technique is a novel arthroscopic rotator cuff repair strategy that restores the anatomy and allows the creation of a tendon-grasping and a bone-grasping construct. The surface area for healing is maximized and early stability is achieved. The technique depends on an anchor that has suture eyelets that allow suture passage in situ and also allows excellent suture sliding. The MDA technique minimizes the number of suture passes through the rotator cuff tissue. We find the technique to be reproducible and simple to use, while optimizing the initial strength and geometry of the rotator cuff repair construct.

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EXHIBIT 5

Docket No.: KFX.003A **Customer No. 20,995**

INFORMATION DISCLOSURE STATEMENT

Applicant	:	Green, et al.
App. No	:	11/143,007
Filed	:	June 1, 2005
For	:	SYSTEM AND METHOD FOR ATTACHING SOFT TISSUE TO BONE
Examiner	:	Nguyen, Anh Tuan Tuong
Art Unit	:	3731

CERTIFICATE OF MAILING

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

January 30, 2007
(Date)

Ryan E. Melnick, Reg. No. 58,621

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Enclosed for filing in the above-identified application is a PTO/SB/08 Equivalent listing 151 references to be considered by the Examiner. Also enclosed are 14 foreign patent references and/or non-patent literature as listed on the Information Disclosure Statement.

This Information Disclosure Statement is being filed before the receipt of a first Office Action on the merits, and presumably no fee is required. If a first Office Action on the merits was mailed before the mailing date of this Statement, the Commissioner is authorized to charge the fee set forth in 37 C.F.R. § 1.17(p) to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 1-30-07

By: _____
Ryan E. Melnick
Registration No. 58,621
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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	11/143,007
	Filing Date	June 1, 2005
	First Named Inventor	Green, et al.
	Art Unit	3731
(Multiple sheets used when necessary)	Examiner	Nguyen, Anh Tuan Tuong
SHEET 1 OF 6	Attorney Docket No.	KFX.003A

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
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Examiner Signature	Date Considered

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U.S. PATENT DOCUMENTS

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U.S. PATENT DOCUMENTS

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	Art Unit	3731
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SHEET 4 OF 6	Attorney Docket No.	KFX.003A

U.S. PATENT DOCUMENTS

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U.S. PATENT DOCUMENTS

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Examiner Initials	Cite No.	Foreign Patent Document *Country Code-Number-Kind Code* Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T[1]
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NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[1]
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